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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MDL NO. 2804

CASE NO. 17-md-2804

Hon. Dan A. Polster

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE CASES

REMOTE VIDEO DEPOSITION OF
DANIEL CHARLES MALONE, PH.D.

May 28, 2021

REPORTED BY: Laura H. Nichols
Certified Realtime Reporter,
Registered Professional
Reporter and Notary Public

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(All Appearing Remotely)

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Consultant for Plaintiffs

Mr. Justin Bond, Videographer
Veritext Legal Solutions

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An Expert Report for the National
Prescription Opiate Litigation, MDL 2804,
Provided by Daniel C. Malone, Ph.D., April
15, 2021

Exhibit 2	17-02
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Attachment 1, Curriculum Vitae of
Daniel C. Malone, Ph.D.

Exhibit 3	17-08
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Article: Perspective, Abusive
Prescribing of Controlled Substances - A
Pharmacy View; The New England Journal of
Medicine

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Exhibit 4 95-15

Email string with attachment, Bates
Numbers ENDO-OPIOID_MDL-06622037 through
ENDO-OPIOID_MDL-06622038.xlsx
(Confidential)

Exhibit 5 124-09

Article: Recommendations for
Selecting Drug-Drug Interactions for
Clinical Decision Support

Exhibit 6 160-23

Article: Designing and Evaluating
Contextualized Drug-Drug Interaction
Algorithms; JAMA

Exhibit 7 210-22

Article: Evaluation of
Machine-Learning Algorithms for Predicting
Opioid Overdose Risk Among Medicare
Beneficiaries with Opioid Prescriptions;
JAMA

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Exhibit 8 223-10

Article: Using Machine Learning to
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Beneficiaries: A Prognostic Study; PLOS
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Exhibit 9 227-23

Malone Billing Hours

Exhibit 10 309-07

PowerPoint: Telecommunication
Standards for Pharmacy and Health
informatics

S T I P U L A T I O N

IT IS STIPULATED AND AGREED, by and between the parties, through their respective counsel, that the deposition of DANIEL CHARLES MALONE, PH.D. may be taken before Laura H. Nichols, Commissioner, Certified Realtime Reporter, Registered Professional Reporter and Notary Public;

That it shall not be necessary for any objections to be made by counsel to any questions, except as to form or leading questions, and that counsel for the parties may make objections and assign grounds at the time of trial, or at the time said deposition is offered in evidence, or prior thereto.

1 I, Laura H. Nichols, a Certified
2 Realtime Reporter and Registered Professional
3 Reporter of Birmingham, Alabama, and a Notary
4 Public for the State of Alabama at Large, acting as
5 Commissioner, certify that on this date, as
6 provided by the Federal Rules of Civil Procedure of
7 the United States District Court, and the foregoing
8 stipulation of counsel, there came before me
9 remotely via Zoom, on May 28, 2021, commencing at
10 10:08 a.m. EDT, DANIEL CHARLES MALONE, PH.D.,
11 witness in the above cause, for oral examination,
12 whereupon the following proceedings were had:

13
14 * * *

15 THE VIDEOGRAPHER: Good morning.
16 Today is May 28th, 2021. We are on the record at
17 10:08 a.m. Today we will take a videotaped
18 deposition in Case Number 17-md-2804. This
19 deposition is being held remotely.

20 Would you please swear the witness.
21

22 DANIEL CHARLES MALONE, PH.D.,
23 having been first duly sworn, was examined and
24 testified as follows:
25

1 EXAMINATION BY MS. FUMERTON:

2 Q. Good morning, Dr. Malone. I
3 introduced myself off the record, but my name is
4 Tara Fumerton, and I represent Walmart in this
5 action.

6 I am going to be the primary
7 questioner on behalf of the other pharmacy
8 defendants, as well as Walmart today, although some
9 other counsel for the pharmacy defendants might ask
10 you questions at some point during the day.

11 Can you please state your full name
12 and spell your last name for the record?

13 A. Daniel Charles Malone, M-A-L-O-N-E.

14 Q. Where do you live?

15 A. Primary residence is in Oro Valley,
16 Arizona.

17 Q. Is that where you are today?

18 A. It is, yes.

19 Q. Okay. And are you giving testimony
20 from your home today?

21 A. Yes, I am.

22 Q. Is anyone else in the room with you?

23 A. No, not at this moment.

24 Q. And do you expect anyone to be in the
25 room with you at any time throughout the day while

1 you are on camera?

2 A. There may be people passing through
3 the common area that I am in, but nobody should be
4 in the room that I am in on a continuous basis.

5 Q. And I don't mean to pry, but are you
6 just talking family members or something along
7 those lines?

8 A. Yeah, yeah, my son and my wife, yes.

9 Q. And you understand that you are not
10 permitted to communicate with your counsel or
11 anybody else while you are giving testimony,
12 correct?

13 A. I do understand that, thank you.

14 Q. And are you --

15 MR. WEINBERGER: So can we just --
16 let me just interject. I said I wasn't going to
17 say much, but I am not his counsel. I am counsel
18 for the plaintiff. I have retained him as an
19 expert, but I am not his lawyer.

20 MS. FUMERTON: Okay. I was going to
21 get to that question, so thank you for that
22 clarification and I will be able to skip that
23 question.

24 Q. (BY MS. FUMERTON:) Are you using
25 your computer today?

1 A. Yes, I am.

2 Q. And so if at any point -- I know it
3 is a little awkward doing this by remote
4 deposition, but if you can't hear me or if you lose
5 connection, please just, as the court reporter
6 said, wave your hands or do something else so that
7 we make sure we have a good connection throughout
8 the day.

9 Do you understand the oath that you
10 just took?

11 A. I do.

12 Q. And you agree to answer every
13 question I ask today truthfully, to the very best
14 of your ability?

15 A. I do.

16 Q. Do you have any notes or materials
17 with you today?

18 A. I have the materials that were
19 provided by, I guess, the -- the docket or the
20 firms -- I get the packets that were sent. So,
21 yes, I have that information.

22 Q. You referenced --

23 A. Yes.

24 Q. You referenced -- just for the
25 record, we had sent you copies of potential

1 exhibits that we might be using at your deposition
2 today.

3 Beyond those documents, do you have
4 any other documents with you today?

5 A. I have a copy of the article that I
6 am assuming is included in the documents that was
7 published in the New England Journal of Medicine.

8 Q. Can you give a little more
9 specificity as to which article you are referring
10 to?

11 A. Yes, one second, please. It is an
12 article by Betses and Brennan in New England
13 Journal of Medicine, Volume 369, Issue 11, from
14 September 12th, 2013.

15 Q. Okay. Do you have any notes on that
16 article?

17 A. No, I have not taken any notes.

18 Q. Okay. And just so that the record is
19 clear, can you actually pull out what is Tab 16 in
20 the material that we sent you. I just want to
21 confirm that that is the same article that you have
22 in front of you.

23 A. Okay.

24 THE REPORTER: 16?

25 A. 16, yes.

1 MS. FUMERTON: Yes. That is going to
2 be marked as an exhibit, although before marking
3 exhibits actually, I want to -- once Dr. Malone
4 gets access to that, we will mark it as an exhibit.
5 But I don't want to mark it as Exhibit 1.

6 Q. (BY MS. FUMERTON:) Is this the
7 document that is the same one that you have in
8 front of you?

9 A. It is, yes.

10 Q. It is identical in all respects?

11 A. I believe so.

12 Q. Okay.

13 MS. FUMERTON: Why don't we take the
14 time to mark some documents as an exhibit. I think
15 before we start, I had you pull out a copy of your
16 expert report. We are going to go ahead and mark
17 that as Exhibit 1.

18 (Exhibit 1 was marked for
19 identification.)

20 Q. (BY MS. FUMERTON:) And I will
21 authenticate it in a little bit, but I am just
22 marking the exhibits right now. And then as
23 Exhibit 2, we are going to mark your CV which I
24 also had asked you to pull out. Do you have those
25 two documents in front of you?

1 A. I do.

2 (Exhibit 2 was marked for
3 identification.)

4 Q. (BY MS. FUMERTON:) Okay. Great.
5 Then let's mark the document that you just pulled
6 out, the New England Journal of Medicine article as
7 Exhibit 3.

8 (Exhibit 3 was marked for
9 identification.)

10 Q. (BY MS. FUMERTON:) Okay. If you
11 just will hold on to those, we will come back to
12 them.

13 Do you have any other documents with
14 you today?

15 A. No.

16 Q. Have you been deposed in the past?

17 A. Not as an expert, no.

18 Q. In what context were you deposed in
19 the past?

20 A. As a plaintiff in a traffic accident
21 in 1987.

22 Q. Is that the only time that you have
23 been deposed?

24 A. Yes, it is.

25 Q. Have you ever testified at trial or

1 other court or legal proceedings, other than the
2 one you just mentioned?

3 A. No.

4 Q. Okay. Well, since 1987 was a while
5 ago, just a few reminders of the deposition
6 process. Please give verbal answers. We can see
7 each other, but the court reporter needs to hear a
8 verbal answer in order to be able to report it.

9 I will do my best not to talk over
10 you or Mr. Weinberger, so if you could please try
11 to wait until I finish a question to give
12 Mr. Weinberger time to object to the question
13 before answering, that would be great. Obviously,
14 our goal is just to create a clear record.

15 If I ask a question that you don't
16 understand, please ask me to rephrase it. And from
17 time to time, Mr. Weinberger might object to some
18 of the questions that I ask. Unless he -- I don't
19 even know that he can instruct you not to answer
20 since he is not your counsel, but unless somebody
21 instructs you not to answer, please go ahead and
22 answer the question despite the objection.

23 Also feel free to take -- or to ask
24 to take a break at any point in time. I will take
25 just regular breaks as we go along, but if for

1 whatever reason we have gone on too long and you
2 need to take a break, please let me know. My only
3 ask is that you answer any pending question before
4 you take the break.

5 Do you have any questions about how
6 this is going to proceed today?

7 A. No, I don't. Thank you.

8 Q. Okay. Is there anything that would
9 prevent you from testifying fully, completely and
10 honestly in this matter today?

11 A. Not that I am aware of, no.

12 Q. Are you taking any medications that
13 might impede your ability to recall information or
14 answer questions honestly?

15 A. No, I am not.

16 Q. What did you do to prepare for your
17 deposition?

18 A. I was provided a list of documents
19 that are listed in my report, so I reviewed those
20 documents. And I also referred to references that
21 I was familiar with through my professional
22 experience, and I guess -- and also read a couple
23 of articles with respect to -- my own articles,
24 with respect to what we had done previously in some
25 of my own research.

1 Q. Anything else?

2 A. No. Well, I'm sorry. I should
3 mention I met with plaintiffs' counsel, so --

4 Q. And who are you referring to as
5 plaintiffs' counsel?

6 A. Mr. Weinberger.

7 Q. Did you meet with anybody else
8 purporting to represent plaintiffs?

9 A. No.

10 Q. Do you have an understanding of who
11 the plaintiffs are in this action?

12 A. I believe so.

13 Q. What is that understanding?

14 A. I believe it is the -- I guess in a
15 broad context, the individuals that have been
16 harmed through the use of opioid -- opioids in, I
17 guess, the state of Ohio is where this particular
18 jurisdiction is, so --

19 Q. Okay. Do you have any more
20 specificity than that as to --

21 A. No.

22 Q. -- who the plaintiffs are in this
23 case? And how did you arrive at that understanding
24 as to who the plaintiffs were?

25 MR. WEINBERGER: Can I just make sure

1 that you are reminded of the fact that anything
2 that came from me, you -- it is within our work
3 product privilege, and you are not to answer
4 questions with respect to any conversations or
5 information you got from me as a result of those
6 conversations.

7 Q. (BY MS. FUMERTON:) So --

8 MR. WEINBERGER: You can say, you
9 know, I had a conversation with Mr. Weinberger,
10 that is fine.

11 MS. FUMERTON: Yeah, I am going to
12 disagree with what Mr. Weinberger expressed a
13 little bit. I think to the extent that you are
14 relying on any information for purposes of your
15 opinion, even if that came from plaintiffs'
16 counsel, you are required to testify about it.

17 But other conversations associated
18 may be covered by the work product privilege that
19 Mr. Weinberger references.

20 Q. (BY MS. FUMERTON:) So I guess if the
21 answer is you learned from plaintiffs' counsel,
22 that is fine. But I will ask my question again --
23 or do you recall what the question was?

24 A. Go ahead and restate the question if
25 you don't mind, please.

1 Q. Sure. I think you said that you
2 understood that the plaintiffs in the action were
3 individuals who were allegedly harmed and residing
4 in the state of Ohio. And my question was how did
5 you arrive at that understanding?

6 A. Yeah. I guess the -- the depositions
7 indicated that the docket -- or I guess the case of
8 the plaintiffs, so -- so reading those documents as
9 part of preparing for my testimony and my expert
10 report, so --

11 Q. Are you referring to the
12 depositions -- oh, I'm sorry.

13 A. Yeah, the depositions that were given
14 by the representatives of the various firms,
15 organizations, yes. Yeah. I have not seen the
16 actual Complaint.

17 Q. Okay. Another one of my questions.
18 So you have not read the Complaint in this matter,
19 correct?

20 A. No, I have not.

21 Q. And so you were just in your deducing
22 from some of the materials that you read in the
23 depositions as to who the plaintiffs were in this
24 action?

25 A. Correct.

1 Q. You mentioned that you met with
2 Mr. Weinberger. How many times did you meet with
3 Mr. Weinberger in preparation for your deposition?

4 A. I believe it was four different
5 meetings in preparation.

6 Q. When was the first meeting?

7 A. Earlier this month. I would have to
8 get out the calendar and look at it. Can I do
9 that?

10 Q. That is okay.

11 A. Okay.

12 Q. I will ask you that -- I think early
13 this month will suffice. How long was that
14 meeting?

15 A. I believe the initial meeting was
16 somewhere between an hour and two hours.

17 Q. And when you refer to the initial
18 meeting, you mean initial meeting for preparation
19 for this deposition, not the first time you met
20 Mr. Weinberger?

21 A. Yes. Your question was about
22 meetings for the deposition. Yes.

23 Q. When was -- was that meeting remote
24 or in person?

25 A. All of my meetings have been remote.

1 Q. Okay. And was there anybody else who
2 participated in that meeting other than yourself
3 and Mr. Weinberger?

4 A. No.

5 Q. When was the next time that you met?

6 A. I believe it was the following week.
7 So I think it was early May.

8 Q. Early on --

9 A. Mid May once and then once last week
10 and yesterday. So basically about, if I remember
11 correctly, once a month -- once a week during the
12 month of May.

13 Q. Okay. And for your meeting, the
14 second meeting that you had in May, was anybody
15 present for that other than -- or did anybody else
16 participate in that other than yourself and
17 Mr. Weinberger?

18 A. No.

19 Q. What about the meeting last week, did
20 anybody participate in that other than yourself and
21 Mr. Weinberger?

22 A. No.

23 Q. And I didn't ask, but that second
24 meeting you had, approximately how long was that?

25 A. Probably similar duration, less

1 than -- less than two hours, between one and two
2 hours.

3 Q. What about your meeting last week,
4 how long was that?

5 A. Similar duration, yeah. Between one
6 and two hours.

7 Q. And yesterday?

8 A. It was less than two hours, probably
9 about an hour and a half.

10 Q. And for the last two meetings, it was
11 just yourself and Mr. Weinberger again?

12 A. That is correct.

13 Q. And for all four meetings, nobody
14 participated in the phone or otherwise listened in,
15 to your knowledge?

16 A. To my knowledge, no.

17 Q. Okay. You said that in preparation
18 for your deposition, you were provided a list of
19 documents that were in your report. Who were you
20 provided those documents -- or who provided you
21 those documents?

22 A. I was given a link to the documents
23 via -- I believe it was a cloud service. And those
24 materials came from, I believe, a law firm -- I
25 could tell you exactly who that is if I was allowed

1 to look at my email. But I believe it came from
2 Dr. -- Mr. Weinberger's office or associated with
3 Mr. Weinberger.

4 Q. Okay. And is every single document
5 that was provided to you in that link referenced in
6 the body of your report itself?

7 A. I believe so, but I did not check
8 through every document that was in those links
9 so --

10 Q. Okay. I am distinguishing this
11 between your report and then your CV, which you
12 obviously have a very lengthy CV with lots of
13 publications. I am excluding those for the moment.
14 But just referring to the documents that are
15 referenced in your expert report. Are those the
16 documents that you were provided?

17 A. Yes.

18 Q. And then you mentioned, I think, that
19 you reviewed some references -- let me back up for
20 a second. In preparation for your deposition, did
21 you review every single one of those documents?

22 A. Yes, I did.

23 Q. Okay. About how long did it take you
24 to do that?

25 A. It was probably in the neighborhood

1 of seventeen hours or so.

2 Q. Is that the first time you had seen
3 those documents?

4 A. It was.

5 Q. And when were you provided that link?

6 A. Early April, I believe, the first
7 week of April.

8 Q. Okay. And so did you re-review those
9 documents in preparation for your deposition?

10 A. I did.

11 Q. And how long did it take you to
12 re-review those documents?

13 A. I didn't re-review all of those
14 documents. So approximately three hours.

15 Q. Do you recall which ones you did
16 re-review?

17 A. There's probably more than forty
18 documents that I looked at, so there's ones that
19 were certainly more prominent and others were less
20 interesting to me.

21 Q. What was more prominent to you?

22 A. The New England Journal of Medicine
23 article that I mentioned previously.

24 Q. That was -- I'm sorry. Is that what
25 has been marked as Exhibit 3?

1 A. Exhibit 3, yes. The materials from
2 CVS specifically. Their 2012 SAS program, looking
3 at computing red flags. They had another SAS
4 program, it appears from 2014 -- again, I guess the
5 title is computing red flags from their dispensing
6 data. So those took the majority of my effort to
7 refamiliarize myself with.

8 Q. Okay. Well, which ones did you find
9 less interesting?

10 A. The documents associated with the
11 certification of the deposition and clerical errors
12 within the deposition so --

13 Q. Okay. I think you also mentioned
14 that you read a couple of articles that you had
15 written. Which articles did you re-review for
16 purposes of your deposition?

17 A. So it would be the article that was
18 published in -- one second here. Let me -- I am
19 referring to my CV.

20 Q. Okay.

21 A. That is Exhibit 2. I will also look
22 at it. I guess I am just taking the time to make
23 sure I am stating it correctly.

24 Q. If there's a particular page, too,
25 that you are looking at, that would be helpful.

1 A. Yeah. Yeah, I will give you that
2 information.

3 So it is Page 12. The first author
4 is Malone, myself. It is the middle of the page,
5 published in Medical Care. It is highlighted with
6 the cursor at the moment.

7 Q. Okay. Any other articles?

8 A. That is the primary one that I looked
9 at. The other one that was, I guess, relevant in
10 this context or somewhat relevant in this context
11 is -- I will find it here.

12 It is on the next page. The first
13 author is Abarca, Jacob. You scrolled down past
14 it, "Computerized Drug-Drug Interaction Alerts."

15 Q. Okay. Any others?

16 A. No.

17 Q. Why did you choose to re-review those
18 two articles?

19 A. I felt they were germane to my
20 experience related to the course -- to the case,
21 excuse me.

22 Q. Was there anything -- any materials
23 that you reviewed in preparation for your
24 deposition that you had not seen before?

25 A. In terms of provided by the --

1 Q. Or to the -- yes -- anything?

2 A. I am sorry. I don't understand your
3 question.

4 Q. Let me ask a better question, and --
5 did you review any documents that aren't mentioned
6 in your report or your CV in preparation for your
7 deposition?

8 A. No.

9 Q. Other than Mr. Weinberger, did you
10 talk to anybody about the testimony that you are
11 going to give today?

12 A. No.

13 Q. Mr. Weinberger has already
14 represented for the record that he is not
15 representing you in your personal capacity for
16 purposes of this deposition. Do you have any other
17 counsel that is representing you in connection with
18 this matter?

19 A. No.

20 Q. If you could grab in front of you
21 Exhibit 1.

22 A. I have it, thank you.

23 Q. And for the record, Exhibit 1 is
24 labeled "An Expert Report for the National
25 Prescription Opioid Litigation, MDL 2804, Provided

1 by Daniel C. Malone, BS Pharmacy, MS, Ph.D., FACMP,
2 Professor, Department of Pharmacotherapy,
3 University of Utah." And it is dated April 15th,
4 2021.

5 Is Exhibit 1 a copy of the report
6 that you submitted in this litigation?

7 A. It is.

8 Q. And it is dated April 15th, 2021,
9 correct?

10 A. That is correct.

11 Q. Is that the date you completed it?

12 A. It is.

13 Q. And if you turn to Page 8 of your
14 report, is that your signature?

15 A. Yes, it is.

16 Q. Is this the only expert report that
17 you have submitted in connection with this matter?

18 A. It is.

19 Q. And if I refer to Exhibit 1 as your
20 report, will you understand what I am referring to?

21 A. I believe so, thank you.

22 Q. Does your report contain a complete
23 and accurate statement of all the opinions you
24 intend to offer in connection with this matter?

25 A. It does.

1 Q. Does your report contain a complete
2 and accurate statement of all of the bases for the
3 opinions you formed in connection with this matter?

4 A. It does.

5 Q. Does your report contain all the
6 facts that you considered in forming your opinions?

7 A. In general, yes. I mean I did not
8 list the specific -- you know, at the detail level
9 based upon what was provided to me, I did not, you
10 know, cite the particular page or statement from
11 the various supporting documents that I reviewed.

12 Q. But if it was a document that you
13 were relying on for purposes of your opinion, you
14 would have included it in your report?

15 A. Yes.

16 Q. Did you talk to anybody in forming
17 your opinions that are set forth in your report?

18 A. No. I did not.

19 Q. In forming your opinions, were you
20 asked to assume any facts?

21 A. No.

22 Q. Did you make any base assumptions in
23 forming your opinions?

24 A. I believe not, no.

25 Q. Did anybody assist you in writing

1 your report?

2 A. No, they did not.

3 Q. Before you signed your report, you
4 reviewed it carefully and ensured that you agreed
5 with all its contents, correct?

6 A. Yes.

7 Q. Do you take full responsibility for
8 all the words that are contained in your report?

9 A. I do.

10 Q. Do you understand all the terms that
11 are used in your report?

12 A. Yes, I do.

13 Q. You issued your report on University
14 of Utah letterhead, correct?

15 A. That is right, as my employer.

16 Q. The University of Utah is not
17 endorsing this report, correct?

18 A. That is correct. That is correct.

19 Q. Have you ever testified as an expert
20 before?

21 A. No, ma'am.

22 Q. Has the Court ever found you
23 qualified to testify as an expert in any capacity?

24 MR. WEINBERGER: Objection to form.
25 Go ahead.

1 A. No.

2 Q. (BY MS. FUMERTON:) Have you ever
3 consulted as an expert before?

4 A. Yes, I have.

5 Q. In what context?

6 A. It was a medication error or adverse
7 event, and I was contacted by a potential
8 plaintiff's lawyer to review the contents of that
9 Complaint.

10 And I rendered an opinion to the
11 plaintiff's attorney about the legitimacy of the
12 Complaint with regards to that medication safety
13 issue.

14 Q. When was this?

15 A. 1994.

16 Q. Do you recall what medication was at
17 issue?

18 A. Yeah, it was an antibiotic called
19 gentamicin.

20 Q. And what ultimately was your opinion,
21 do you recall?

22 MR. WEINBERGER: Objection. But go
23 ahead.

24 A. The plaintiffs had asked if the
25 pharmacist had been contributory to the

1 individual's injuries, and my conclusion was they
2 had not.

3 Q. (BY MS. FUMERTON:) We are going to
4 come back to your report in more detail.

5 If you could put in front of you what
6 has been previously marked as Exhibit 2.

7 A. I have it.

8 Q. And for the record -- great. For the
9 record, this was an attachment, Attachment 1 to
10 your expert report; is that correct?

11 A. Yes. Yes, it is.

12 Q. And is this a true and accurate copy
13 of your current CV?

14 A. Yes, it is.

15 Q. Is all the information contained in
16 it accurate as of today?

17 A. As far as I know, yes.

18 Q. Did you prepare Attachment 1?

19 A. Yes, I did.

20 Q. It has a date of March 2021; is that
21 when you prepared it?

22 A. I update it every time with those
23 dates, every time I make edits to the document. So
24 that was the last time I had edited the document.
25 This document has been, I guess, edited since

1 probably 1995 continuously.

2 As I have a new publication occur, I
3 add it to the document, or new paper that is
4 accepted for a meeting, I add it to the document.
5 So it is continuous -- it is a dynamic document in
6 that regard.

7 Q. Does it contain all of your
8 employment history post pharmacy school?

9 A. No, it doesn't. It contains --

10 Q. Okay. Earlier I asked if it was true
11 and accurate. I guess my question is do you know
12 offhand what is missing from your CV?

13 A. So my current version of my CV
14 represents my academic work experience primarily.
15 Since I guess the majority of what is represented
16 in that document represents my graduate,
17 postgraduate and employment after obtaining my
18 pharmacy degree.

19 Q. Okay. You are currently a professor
20 in the Department of Pharmacotherapy in Skaggs
21 College of Pharmacy at the University of Utah,
22 correct?

23 A. That is correct.

24 Q. And am I butchering how you pronounce
25 that department name?

1 A. Pharmacotherapy. No, you are not.

2 Q. And pharmacotherapy refers to the
3 medical treatment by means of drugs; is that right?

4 A. Generally speaking, that would be a
5 good characterization.

6 Q. Would you characterize it
7 differently?

8 A. Not necessarily, no.

9 Q. And you have held your position at
10 the University of Utah since October of 2019,
11 correct?

12 A. That's correct.

13 Q. And I am going to ask you a series of
14 questions. Feel free to refer to your CV as
15 necessary, but if you can answer them off the top
16 of your head, feel free to do that too.

17 A. Okay.

18 Q. You began your career in academia in
19 1993; is that right?

20 A. That is correct.

21 Q. And that is almost thirty years ago,
22 right?

23 A. That's correct, yeah.

24 Q. So you have been employed in academia
25 for the last almost thirty years?

1 A. That is correct, yeah.

2 Q. You started as a research associate
3 in 1993 at the School of Pharmacy at the University
4 of Washington, correct?

5 A. That is correct.

6 Q. And then you moved to an assistant
7 professor of pharmacy at the University of Colorado
8 Health Center -- excuse me, University of Colorado
9 Health Science Center in October of 1994, correct?

10 A. That is correct.

11 Q. And can you please explain what the
12 difference is between an assistant professor and a
13 professor?

14 A. Well, there's three levels of rank in
15 the academic world: There's assistant, associate
16 and full professor. So assistant professor
17 generally means without tenure, there's no
18 guarantee of a position within the organization.
19 So -- and all new hires, generally speaking, coming
20 out of their graduate studies or post-doctoral
21 fellowship experiences are hired at the assistant
22 level. So it is the lowest level.

23 The next level is associate level,
24 and that is an individual who has been employed for
25 usually a period of five to six years. They

1 undergo both an internal and external peer review
2 of their accomplishments and skills. And assuming
3 satisfactory performance, and I will use the term
4 "satisfactory" fairly loosely here. Actually
5 there's a fairly high level of performance expected
6 in order to move to the associate level.

7 After, again, a period of time,
8 the -- an individual can submit to be granted
9 professor title. So no stipulation. And, again,
10 internal and external review of the candidate's
11 accomplishments is conducted, and pending
12 successful review of that, the person is promoted
13 to what is considered a full professor, which,
14 therefore, we drop the title "assistant" or
15 "associate."

16 Q. As used in your CV, when you are
17 listed as an associate professor, is that a tenured
18 track position, or is that a tenured position, not
19 tenured track? Let me rephrase the question.

20 Is the associate professor title in
21 your CV represented as a tenured position?

22 A. It does.

23 Q. And what is the typical length of a
24 tenure track position?

25 A. As in the length to obtain a tenured

1 position?

2 Q. Yes, what is the typical length?

3 A. Again, it is five or six years. It
4 could be seven, depending upon the institution.

5 Q. Okay. So you started off as
6 assistant professor of pharmacy, and was that a
7 tenured track position then?

8 A. It was a tenured -- I'm sorry. The
9 initial position I accepted at the University of
10 Colorado was not tenured track, but I switched to
11 tenured track after two years.

12 Q. Okay.

13 A. So not -- not all assistant professor
14 positions are tenure tracked.

15 Q. Okay. And so you were an assistant
16 professor at the University of Colorado for about
17 six years, correct?

18 A. Five years, yes. From '94 to '99,
19 yeah. Yeah.

20 Q. Okay. And then you moved to become
21 an assistant professor at the University of
22 Arizona, correct?

23 A. That is correct.

24 Q. And was that a tenured track
25 position?

1 A. It was.

2 Q. And you did not obtain tenure at the
3 University of Colorado, correct?

4 A. I did not apply for tenure, no.

5 Q. You were an assistant professor at
6 the University of Arizona for almost two years; is
7 that right?

8 A. I believe so, yes.

9 Q. And then in July of 2001, you were
10 promoted to associate professor; is that right?

11 A. It has been a long time. So I have
12 to even look myself to see when I was promoted.

13 (Pause.)

14 A. Yes, that is correct.

15 Q. (BY MS. FUMERTON:) And did you get
16 tenure at that time in July of 2001?

17 A. No, I did not. It was a delayed
18 tenure clock. I was promoted without tenure, and I
19 received tenure two years later.

20 Q. Why was it a delayed tenure clock?

21 A. Be -- so when you change
22 institutions, organizations, they don't want to
23 tenure somebody they don't know, generally
24 speaking. So technically my clock as assistant
25 professor started over when I changed institutions.

1 So I --

2 Q. Why did you change -- I'm sorry. Go
3 ahead.

4 A. So when I joined the University of
5 Arizona, my tenure clock started at zero, and I was
6 given six years to demonstrate my skills and my
7 abilities to become tenured. So after two years, I
8 went up for promotion, and two years later I was
9 promoted -- or I was granted tenure.

10 Q. So were you granted tenure in 2003?

11 A. I believe that is correct.

12 Q. Why did you move from the University
13 of Colorado to the University of Arizona?

14 A. Two primary reasons. The research
15 group at the University of Arizona was recognized
16 as one of the top research groups in the nation.
17 And the second reason is the colleagues that I had
18 at University of Arizona were individuals that I
19 had known and I wanted to work with the specific
20 individuals.

21 Q. Which individuals are those?

22 A. The two faculty members were Brenda
23 Motheral and Emily Cox.

24 Q. Were you told at the University of
25 Colorado that you would not make tenure?

1 A. No. In fact, my third-year review
2 suggested that I was in the process of -- or at
3 least I had a very positive three-year review for
4 tenure.

5 Q. So I think, if my notes are correct,
6 your best recollection is that you obtained tenure
7 in July of 2003, approximately --

8 A. Uh-huh.

9 Q. -- at the University of Arizona. And
10 then were you promoted in July 2006 to become a
11 full professor at that time?

12 A. Yes, I was, uh-huh.

13 Q. And you were also an associate
14 professor at the College of Public Health, correct?

15 A. Yes. That was an affiliated title,
16 yes.

17 Q. And so what does an affiliated title
18 mean? Was that a dual appointment, or how does
19 that work?

20 A. It was a nonfunded position. So they
21 didn't support my salary, and it allowed me to
22 support their mission and goals within the College
23 of Public Health.

24 Q. Okay. And then your next job is back
25 where you are now, which is the University of Utah

1 in October of 2019, correct?

2 A. Correct. I was at the University of
3 Arizona for twenty years and then moved, yes.

4 Q. And why did you move to the
5 University of Utah in October of 2019?

6 A. Again, it had to do with the
7 availability of colleagues that were doing the type
8 of research that I was interested in doing.

9 Q. And who are those colleagues that
10 were doing the work that you were interested in
11 doing?

12 A. With the Department of Biomedical
13 Informatics at the University of Utah, Ken Kawamoto
14 and Guilherme Del Fiol are the two principals. In
15 addition, there's a post-doctoral fellow that they
16 had hired named Thomas Reese that had been involved
17 in some of my earlier research remotely. So I had
18 hoped to work with him with my move to Utah.

19 Q. And what was the work that you were
20 interested in doing?

21 A. It is continuation of my primary
22 research, is preventing drug-drug interactions.

23 Q. I will have some questions about that
24 later on but wanted to round out your background.

25 So I want to switch gears a little

1 bit to just your education. You obtained a BS in
2 pharmacy in 1987 from the University of Colorado,
3 correct?

4 A. That is correct, yes.

5 Q. And is that a four-year program, a
6 six-year program? How does that work?

7 A. It was a five-year program. And
8 the -- the general education of pharmacists at that
9 period of time was a minimum of two years prior to
10 admittance to the program and three years in the
11 program. Because I had changed degree paths, it
12 took me six years from my initial entry into
13 college to finishing that program.

14 Q. What was your initial degree path?

15 A. Undecided. So I explored various
16 degree paths, including geology, journalism, radio,
17 television, film.

18 Q. So you were at the University of
19 Colorado in an undergraduate capacity for six
20 years; is that right?

21 A. No, it is not. I spent two years --
22 at that time, it was called Mesa State, which is a
23 four-year degree-granting institution in Grand
24 Junction, Colorado. I did two years there, and
25 then four years at the University of Colorado.

1 Q. Did you go directly from Mesa State
2 to the University of Colorado?

3 A. I did. In 1983.

4 Q. In 1983. Did you go directly to Mesa
5 State out of high school?

6 A. Yes, I did.

7 Q. Where did you attend high school? We
8 won't go back to elementary school.

9 A. That is good because I moved a lot
10 when I was a kid. I went to high school in Grand
11 Junction, Colorado at Grand Junction Central.

12 Q. But in all seriousness, I actually
13 was going to ask that question as sort of where you
14 grew up, what area of the country?

15 A. I grew up in Colorado. My father
16 worked for the Department of Agriculture, so we
17 moved about every two years.

18 Q. But within Colorado?

19 A. All within Colorado, yes.

20 Q. In 1990 you obtained an MS in Health
21 Outcomes at the University of Texas at Austin,
22 correct?

23 A. That is right.

24 Q. So did you go directly from the
25 University of Colorado to the University of Texas?

1 A. No, I did not.

2 Q. Okay.

3 A. I worked -- I'm sorry. I worked as a
4 pharmacist in a hospital in Pueblo, Colorado. I
5 also did relief work as a pharmacist at various
6 pharmacies in Southern Colorado.

7 Q. I want to talk more about your
8 experience as a practicing pharmacist too. But
9 just so my notes are clear, so in 1987 you did --
10 between 1987 and 1990 you worked as a pharmacist in
11 various capacities; is that right?

12 A. From 1987 to 1993 I worked as a
13 pharmacist in various capacities.

14 Q. So you worked as a pharmacist while
15 you were pursuing your master's?

16 A. And Ph.D. as well, yes.

17 Q. Okay.

18 A. Just on a part-time basis.

19 Q. Going back to your MS in Health
20 Outcomes at the University of Texas, what is Health
21 Outcomes?

22 A. It is a general area of research
23 having to do with the intersection of health
24 interventions and the associated results of those
25 interventions in terms of everything from economic,

1 reducing healthcare costs or increasing healthcare
2 costs all the way through patient-reported
3 outcomes: Satisfaction, quality of life, symptoms
4 of disease, resolution of symptoms of disease. So
5 it is a very broad term. Encompasses a lot of
6 discipline -- applied disciplines.

7 Q. Would you agree that the focus on
8 health outcomes is improving the health of society?

9 A. I would agree with that statement,
10 yes, generally.

11 Q. Do you agree that managing pain is
12 one of those goals?

13 A. Yes.

14 Q. Did you write a master's thesis to
15 obtain your MS?

16 A. I sure -- yes, I did.

17 Q. What was the topic of that master's
18 thesis?

19 A. It was to look at a program where we
20 instituted additional services within community
21 pharmacies to improve patient satisfaction. And, I
22 guess, my thesis focused on the patient
23 satisfaction, but there are other components of
24 that program that examined other attributes, such
25 as pharmacy performance, you know.

1 Q. Was your master's thesis focus at all
2 on opioids?

3 A. No, it was not specifically to
4 opioids.

5 Q. And in 1993, you obtained your Ph.D.
6 in Health Outcomes, correct?

7 A. Yes, I did.

8 Q. And what was the topic of your
9 dissertation?

10 A. It was associated with
11 medication-associated adverse events, and
12 litigation around those adverse events, and the
13 effect of that litigation on pharmaceutical
14 manufacturers.

15 Q. Did that involve opioids?

16 A. I don't recall that opioids were a
17 part of any of the attributes that I looked at at
18 that particular time.

19 Q. And then from 1993 to 1994, I believe
20 your CV lists you as a post-doctoral fellow at the
21 University of Washington?

22 A. Uh-huh.

23 Q. Is that right?

24 A. That is correct.

25 Q. And did that overlap with your

1 position as a research assistant at the University
2 of Washington?

3 A. Yeah, they are dual appointments,
4 yes.

5 Q. And what was your area of research at
6 that time?

7 A. Varied. I worked with -- again,
8 along the similar lines of health outcomes, but we
9 were looking at the effect of medications on
10 patients' symptoms and -- in a general context and
11 also the economics associated with using those
12 medications in those particular disease states.

13 So it included clinical trial
14 research. It included developing patient-reported
15 outcomes, tools and measures to capture patient
16 satisfaction and medication adherence.

17 Q. You mentioned that you were studying
18 the effect of medications. Were any of those
19 medications opioids?

20 A. No.

21 Q. And I see that you have an -- acronym
22 is probably the wrong word, but a title after your
23 last name which is FACMP. What does that stand
24 for?

25 A. I am a Fellow of the Academy of

1 Managed Care Pharmacy. So Managed --

2 Q. And what does that --

3 A. The Academy of Managed Care Pharmacy
4 is an organization that represents pharmacists that
5 work in managed care. So these are generally
6 represented by pharmacy benefit managers, health
7 insurance organizations, other organizations that
8 examine medication use at a population level or
9 provide drug benefits at a population level. So I
10 am a fellow of that academy.

11 Q. And when did you become a fellow of
12 that academy?

13 A. That is -- off the top of my head, I
14 think it was 2014-2015, if I remember correctly.
15 It has been a while.

16 Q. Your CV is very long. Is it listed
17 in your CV? I might have missed it, in full
18 disclosure.

19 A. It may be at the back. Hang on one
20 second. 2013. It is listed on Page 49 at the
21 bottom of the page.

22 Q. And how does one become a fellow
23 of --

24 A. Oh, there is --

25 THE REPORTER: I couldn't hear you.

1 You overlapped.

2 Q. (BY MS. FUMERTON:) Sure, I will just
3 repeat my question.

4 How does one become a fellow of the
5 Academy of Managed Care Pharmacy?

6 A. There's a set of criteria that one
7 needs to fulfill and apply to become a fellow. It
8 includes attributes of involvement in the
9 organization, research or activities associated
10 with, I guess, the mission objectives that the
11 organization -- that align with the mission of the
12 objectives of the organization.

13 My primary reason for being selected
14 as a fellow was my research related to the practice
15 of pharmacy.

16 Q. And who selects you? So what is the
17 nomination process?

18 A. It is done by a committee within the
19 organization, within the academy. So there's a --
20 I guess I would best describe it as a peer,
21 individuals who evaluate a person's application.

22 Q. And you mentioned application. So do
23 you apply to become a fellow?

24 A. You have to apply to become a fellow,
25 yes.

1 Q. And what does that application
2 entail?

3 A. Providing documentation of your
4 activities, as mentioned previously, so, you know,
5 what committees I have served on with the
6 organization, what contributions I have made to the
7 organization, publications, presentations,
8 experience in the -- associated with the field that
9 the organization represents.

10 Q. Do you hold any other professional
11 certifications, titles or licenses?

12 A. At one point in time, I was an
13 emergency medical technician, so EMT. But beyond
14 that, I cannot recall any.

15 Q. When were you an EMT?

16 A. 1986 to 1989.

17 Q. Have you ever faced any disciplinary
18 actions in your field?

19 A. From -- could you qualify
20 disciplinary?

21 Q. Say it in the broadest sense, meaning
22 disciplinary from sort of a reprimand, a warning,
23 an investigation into conduct.

24 A. Okay.

25 Q. How --

1 A. I indirectly dispensed a medication
2 one time, so my immediate supervisor told me about
3 that.

4 Q. When was that?

5 A. It was probably 1990.

6 Q. What was the medication?

7 A. I don't recall.

8 Q. Who was your employer?

9 A. Walgreens.

10 Q. Do you recall how you incorrectly
11 dispensed it?

12 A. It was the -- just the wrong -- a
13 similar name on the shelf, so the wrong bottle was
14 selected.

15 Q. Was there an adverse event --

16 A. No, the patient never took -- no, the
17 patient never took the medication.

18 Q. Anything -- any other disciplinary
19 actions that you have ever faced --

20 A. No.

21 Q. -- either as a pharmacist or in
22 academia?

23 A. No.

24 Q. Have you ever had any license
25 revoked?

1 A. No.

2 Q. Have you ever been convicted of a
3 crime other than a misdemeanor traffic violation?

4 A. No.

5 Q. I am going to switch subjects a
6 little bit to your experience as a pharmacist, and
7 we have been going for a little bit over an hour,
8 so why don't we take just a ten-minute break and
9 get back started, if that works?

10 A. That is fine. Thank you.

11 THE VIDEOGRAPHER: Okay. We are off
12 the record at 11:07.

13 (Whereupon, a break was had from
14 11:07 a.m. until 11:37 a.m. EDT)

15 THE VIDEOGRAPHER: We are back on the
16 record at 11:37.

17 MS. FUMERTON: I was just saying,
18 just for the record, Mr. Weinberger had some
19 internet issues, we took a little bit of a longer
20 break, but I think we are all set now hopefully and
21 moving forward, so we will continue.

22 Q. (BY MS. FUMERTON:) Dr. Malone, I
23 want to talk a little bit about your experience as
24 a pharmacist now. Are you a licensed pharmacist?

25 A. At the moment, no, I am not. And

1 pardon the interruption on your line of
2 questioning. I want to clarify one of my previous
3 statements from earlier.

4 You asked me about which documents I
5 looked at. There were two documents that are not
6 in my report that I have looked at since my report
7 was written. One of them is a document that was
8 generated by Carmen Catizone in response to this
9 particular litigation, I believe. And the second
10 is a document produced by the State Board of
11 Pharmacy for Ohio, from the State of Ohio,
12 regarding a survey that was conducted, I believe
13 last year, about pharmacists' work experiences.

14 So I have received both those
15 documents.

16 Q. Okay.

17 A. My apologies for failing to mention
18 them. They are not in my report and didn't pertain
19 to the basis of my report, but I just wanted to
20 clarify that for the record.

21 Q. Okay. And so you did not rely on
22 those for purposes of your report, correct?

23 A. No, I did not, no.

24 Q. Okay. So I think I was asking you,
25 you were a licensed pharmacist, and I think you

1 said you are not currently?

2 A. That's correct.

3 Q. And so, according to your report, it
4 states that you had a pharmacist's license that was
5 active in Colorado until 2019. Is that an accurate
6 statement?

7 A. That is correct.

8 Q. And so when did you first obtain that
9 license in Colorado?

10 A. In, I believe, July of 1987.

11 Q. So from July 1987 until -- do you
12 know what month in 2019?

13 A. I believe it was October.

14 Q. Until October of 2019, you were a
15 licensed pharmacist in Colorado, correct?

16 A. I am sorry. No, until 2018, I was a
17 licensed pharmacist. And my apologies, that
18 that -- and -- let me back up here.

19 I relinquished --

20 Q. Are you referencing something that
21 would be helpful for us to look at too?

22 A. I am looking at my CV, and my CV has
23 it wrong too. So on Page 51 of my CV, pharmacy
24 licensure, there -- because I don't practice, have
25 not practiced pharmacy for quite some time. I

1 guess I forgot to update this.

2 I was licensed in the state of
3 Colorado up through 2018 and licensed in the state
4 of Texas to practice pharmacy up through 2019. It
5 currently says present, so please correct that
6 error.

7 Q. Okay. So let's just make sure that
8 the record is clear. So you were a licensed
9 pharmacist in Colorado from 1987 to 2018. Is that
10 correct?

11 A. That's correct. That's correct.

12 Q. And is that -- and is that your
13 correct pharmacist license number listed in your
14 CV?

15 A. That was the license number I was
16 issued, yes.

17 Q. And were you licensed continuously
18 from 1987 to 2018?

19 A. Yes, I was.

20 Q. Okay. And then with respect to
21 Texas, you obtain that pharmacy license in 1988; is
22 that correct?

23 A. That is correct.

24 Q. And that -- you held that license
25 until 2019? Is that correct?

1 A. Yes. November 30th, 2019.

2 Q. And where are you getting the
3 November 30th date from?

4 A. That is the date that my license
5 expired because I didn't renew it.

6 Q. Oh, you just knew that? I didn't
7 know if you were looking at something. You just
8 remember that --

9 A. No. No. I just know that off the
10 top of my head. Sorry, Nicole -- or Laura, I'm
11 sorry.

12 Yes, I knew that off the top of my
13 head because it was recent.

14 Q. Okay. So turning to Exhibit 1, which
15 is your report, Page 1 in the first paragraph --

16 MS. FUMERTON: I don't know, Kristin,
17 if we can pull it up.

18 Q. (BY MS. FUMERTON:) But you say, if
19 you are following along, Dr. Malone, in the first
20 paragraph on Page 1, the last sentence says, "Since
21 1983 I have pursued an academic career but kept my
22 licenses active until 2019 (Colorado) and 2020
23 (Texas)." That statement is incorrect, right?

24 A. Thank you for pointing that out.
25 Actually, that statement is correct; what I just

1 said was wrong. I apologize, the years kind of run
2 together here.

3 No, I let the Colorado license lapse
4 in '19 -- I let the Texas license, again, because I
5 knew that November 20th or 30th date -- just last
6 fall. So I'm sorry, yeah. So we are in 2021. So
7 that statement is correct. My CV is the one that
8 is incorrect. So my apologies on that.

9 Q. Okay. But let's be clear. I think
10 you had just testified, so with respect to the
11 state of Texas, your current testimony is now that
12 your pharmacy license was active from 1988 to
13 November 30th, 2020; is that correct?

14 A. That's correct, yes. My apologies
15 for the misstatement.

16 Q. And earlier you testified that you
17 let your license -- your license expired for
18 Colorado in 2018. Are you saying now that that is
19 2019?

20 A. That's correct, yes.

21 Q. So your CV is incorrect as far as
22 your licensure status?

23 A. Yes.

24 MR. WEINBERGER: Objection, form.

25 Q. (BY MS. FUMERTON:) But your report

1 is accurate?

2 A. That is correct, yes.

3 Q. You mentioned it has been a long time
4 since you have practiced as a pharmacist. In fact,
5 you have not practiced as a pharmacist in almost
6 thirty years, correct?

7 A. Almost twenty-eight years since I
8 have worked as a pharmacist, correct.

9 Q. And the last time that you practiced
10 in pharmacy was in 1983, correct?

11 A. Correct.

12 Q. And for your entire career, you have
13 practiced as a pharmacist for less than six years
14 in total; is that right?

15 A. That's correct.

16 Q. And you first started practicing as a
17 pharmacist in 1987; is that correct?

18 A. That is.

19 Q. And you earlier testified that when
20 you went into the master's program in 1990, you
21 started practicing part-time, correct?

22 A. Yes.

23 Q. From 1987 to 1990 when you entered
24 that program, did you work as a pharmacist
25 full-time?

1 A. From 1987 to 1988, I worked as a
2 pharmacist full-time.

3 Q. And what does "full-time" mean?

4 A. Forty hours a week or more.

5 Q. And then what happened in 1988?

6 A. I started graduate school at the
7 University of Texas.

8 Q. I have my dates -- I apologize --
9 slightly off. So in 1988 you began graduate
10 school, and you started working part-time as a
11 pharmacist then; is that right?

12 A. I started working as a pharmacist
13 part-time in the fall of 1988.

14 Q. And you continued to work part-time
15 as a pharmacist from fall of 1988 until 1993; is
16 that right?

17 A. That is correct. That is correct.

18 Q. And when you say part -- when you say
19 part-time, how many hours per week, approximately,
20 were you working as a pharmacist during those
21 years?

22 A. Approximately twenty.

23 Q. For that entire time period, from
24 1988 -- from fall of 1990 -- let me start over.

25 When you say that it was

1 approximately twenty hours per week, was that for
2 the entire time period from the fall of 1988 until
3 1993?

4 A. I believe so.

5 Q. Did it vary at all?

6 A. Of course.

7 Q. What about through the summer months,
8 did you work more than, less than, or were you
9 always just working the maximum of about twenty
10 hours per week?

11 A. The amount of work that I did
12 depended upon the pharmacy operations that I was
13 working for and their needs. And if somebody would
14 call in sick, I would go in and fill in a shift.

15 In addition to my normal duties, I
16 would also work at semester breaks occasionally,
17 like over the holidays, provide extra relief during
18 those times.

19 Q. And so if you -- I'm sorry. I didn't
20 mean to interrupt you. Go ahead.

21 A. I was going to say, so the amount of
22 work would vary depending on the demands, and
23 usually I supported more than one organization as a
24 pharmacist.

25 Q. Okay. What would the range be, if

1 you were to give one, as far as the least amount
2 you would work during a week to sort of the most
3 you would work during a week?

4 A. From zero to probably fifty hours.

5 Q. So let's talk about when you were a
6 full-time pharmacist from 1987 to 19 -- until the
7 fall of 1988. So did you work, just to put a
8 little finer point on it, from the fall of 1987 to
9 the fall of 1988, basically one year, as a
10 full-time pharmacist?

11 A. I started in -- my position in June
12 of 1987 and worked through August of 1988 at a
13 hospital in Colorado.

14 I also at times supported other
15 retail pharmacy operations in the Southern Colorado
16 area during that time frame.

17 Q. What other retail pharmacy operations
18 in Southern Colorado did you support during that
19 time frame?

20 A. Independent pharmacy that was located
21 in Pueblo and also Walmart located in Canyon City
22 and Salida, Colorado.

23 Q. Okay. So still focusing on the time
24 period between June 1987 to August 1988, you worked
25 as a pharmacist at a hospital in Colorado. What

1 was the name of that hospital?

2 A. St. Mary-Corwin.

3 Q. And were you working full-time at St.
4 Mary-Corwin?

5 A. Yes.

6 Q. You also mentioned during that time
7 frame you worked for an independent pharmacy. What
8 was the name of that independent pharmacy?

9 A. I don't recall.

10 Q. Tab 1 -- I'm sorry, Exhibit 2 which
11 is your CV, at 51 lists a number of pharmacies.
12 Would that refresh your recollection as to what
13 pharmacy that was?

14 A. That pharmacy is not on that list.
15 The primary ones -- the primary pharmacies I worked
16 at are shown on Page 51.

17 Q. Okay. So --

18 A. When I say primary, ones that I
19 worked more than just, you know, probably eighty to
20 a hundred hours at.

21 Well, let me clarify that. Yeah,
22 that statement is probably accurate. Well, that is
23 not quite true. There was another hospital that I
24 worked at over that time frame that I probably
25 worked more than eighty hours at, so --

1 Q. Okay.

2 A. So this is not a complete listing of
3 every pharmacy I worked at.

4 Q. This is a list of the main pharmacies
5 that you worked at, correct?

6 A. Uh-huh.

7 Q. Would you say that you were a relief
8 pharmacist at any of the other ones that are not
9 listed here?

10 A. Yes.

11 Q. You worked at those part-time if they
12 weren't listed here?

13 A. Correct.

14 Q. And you specifically mentioned
15 Walmart. You worked at Walmart as a relief
16 pharmacist for less than two months, correct?

17 A. Hard to quantify in terms of time,
18 just from the standpoint that I filled in at the
19 store in Canyon City over the course of several
20 months in the summer of 19 -- I believe
21 spring/summer of 1988. And then I guess there was
22 a discrepancy that basically -- they needed relief
23 help in winter of 19 -- I guess it was winter of
24 1988 as well.

25 So -- but, you know, probably less

1 than twenty total shifts at Walmart over that time
2 frame.

3 Q. Less than twenty shifts, is it fair
4 to say were fewer than two or three months?

5 THE REPORTER: Were fewer than --

6 Q. (BY MS. FUMERTON:) -- two to three
7 months?

8 A. No. Because it encompassed all the
9 way to the end of the year, 1988.

10 Q. Okay.

11 A. I worked between Christmas and New
12 Year's at the Walmart in Salida, Colorado.

13 Q. How long was a typical shift?

14 A. Well, the pharmacy would typically
15 open at 9:00 in the morning and go to 6:00 in the
16 evening at those times, so -- and there was no
17 lunch break or any relief. You know, so that was
18 continuous.

19 Q. So you have not worked at a Walmart
20 pharmacy since the winter of 1988, correct?

21 A. That's correct.

22 Q. Do you know what ConnexUs is?

23 A. I believe it is a software program,
24 but I am not sure.

25 Q. Okay.

1 A. I believe that is Walmart's software
2 program.

3 Q. You have never used ConnexUs,
4 correct?

5 A. That's correct. When I worked for
6 Walmart -- when I first started working with
7 Walmart, we used a typewriter.

8 Q. Okay. So you mentioned that on Page
9 51 of Exhibit 2, which is your CV, these were the
10 main pharmacies that you practiced at. Do you
11 recall the names of any other pharmacies that you
12 have practiced with?

13 A. The names, no. There were a couple
14 of independent pharmacies in Austin, Texas that
15 asked me to come in and do relief work on occasion
16 because pharmacists were either sick or needed
17 relief for various other reasons. Those were
18 usually limited in duration to a single shift or a
19 couple of shifts, cover a weekend.

20 Q. With respect to Walgreens --

21 A. Specific names of those -- I'm sorry.
22 The specific names of those pharmacies --

23 Q. It is my fault.

24 A. The specific names of those
25 pharmacies, I don't recall. It has been a long

1 time.

2 Q. With respect to Walgreens, your CV
3 lists your working there from 1988 to 1989. Do you
4 recall the specific months where you began and
5 left?

6 A. I believe it was August of 1988, and
7 I don't recall the month in 1989. I think they
8 continued to use me occasionally after 1989 to
9 support them, but I wasn't on -- I think, as I
10 said, I don't recall being on their schedule on a
11 regular basis.

12 Q. You worked for them for approximately
13 a year on a part-time basis, correct?

14 A. Approximately, yes.

15 Q. You have never worked on site at a
16 Rite Aid pharmacy, correct?

17 A. That's correct.

18 Q. And you have never worked for a CVS
19 pharmacy, correct?

20 A. That's correct.

21 Q. You also have never worked for a
22 Giant Eagle pharmacy, correct?

23 A. Yes.

24 Q. And with respect to Rite Aid, CVS and
25 Giant Eagle, you have never worked for any of those

1 entities in any other capacity, correct?

2 A. Correct.

3 Q. And with respect to Walmart, other
4 than a few months, less than twenty shifts, back in
5 the late '80s, you have never worked for Walmart in
6 any other capacity, correct?

7 A. That's correct.

8 Q. And other than what you described as
9 your work for Walgreens, you have never worked for
10 them in any other capacity, correct?

11 A. That's correct.

12 Q. You have never worked in the home
13 office of any pharmacy company, correct?

14 A. That's correct.

15 Q. And you have never worked in a data
16 governance function of any pharmacy company,
17 correct?

18 A. Correct.

19 Q. You were not relying on your
20 experience at Walmart in forming any of your
21 opinions in this case, correct?

22 A. That is correct.

23 Q. And you are similarly not relying
24 on --

25 A. I'm sorry. Let me restate that.

1 Except for at the time I worked for
2 Walgreens, and I think it is still true today, they
3 used a centralized computer system for processing
4 prescriptions and have continued to use a
5 centralized computer system for processing
6 prescriptions.

7 So that knowledge, I don't think --
8 which I gained in 1988, I think still remains
9 relevant to my opinions.

10 Q. So let me make sure the record is
11 clear. When we did this the first time, this
12 happened that Walmart and Walgreens got confused.
13 So my question was originally that you were not
14 relying on any of your experience at Walmart in
15 forming any of your opinions in this case, correct;
16 and you said that's correct. You are not changing
17 that testimony, correct?

18 A. You are stating that correctly, yes.
19 I am stating -- I was trying to clarify my
20 experience at Walgreens and the fact that
21 Walgreens, in -- when I worked for that
22 organization, began working for that organization,
23 and up through the materials that I reviewed for
24 this case, it appears that they have maintained a
25 central pharmacy server to maintain pharmacy

1 records or computer system to maintain pharmacy
2 records. And I relied on that information as part
3 of the bases for my opinions.

4 Q. Right. But your only experience with
5 Walgreens, to be clear, is back in the late 1980s
6 and the materials then you reviewed that are listed
7 in your report, correct?

8 A. So if you define "experience" as
9 employment, you are correct. I have interacted
10 with Walgreens from a research standpoint since
11 that time, and we have published papers together.

12 Q. I am going to get into that a little
13 bit later, too, but what specifically are you
14 thinking of, in what area of research?

15 A. We -- I worked with, at the time,
16 Carl Bertram with Walgreens and their database to
17 look at dispensing associated with medications for
18 individuals. I believe it was -- the purpose of
19 that particular study examined issues in gender
20 utilization of medications.

21 Q. You said at that time -- (audio
22 distortion).

23 A. Quite frankly --

24 MR. WEINBERGER: Tara -- Tara, you
25 have a tendency to not let him -- I mean it is not

1 frequent, but let him finish his answer, please,
2 before you get into your question. Thanks.

3 MS. FUMERTON: Sure. I apologize if
4 I am interrupting you. It is not my intent.

5 A. So I am trying to find the particular
6 article that we published. It was back in the
7 2000s decade, if I remember correctly. And I don't
8 know if it actually went to a publication or if it
9 was just a podium -- or a meeting presentation.

10 Oh, here it is. Yeah, so this was
11 Page 12 of Exhibit 2, top of Page 12. First author
12 is Anthony. Second author is Lee. Third author is
13 Bertram. We published a paper using data from
14 Walgreens at that time frame.

15 Q. (BY MS. FUMERTON:) Did that data
16 involve opioids at all?

17 A. It probably did involve opioids, but
18 I don't recall. It wasn't focused on opioids,
19 so --

20 Q. So since leaving the pharmacy
21 practice in 1993, have you done any continuing
22 education to maintain your licenses?

23 A. Definitely.

24 Q. And describe generally what that
25 would entail.

1 A. Each state board sets forth their
2 requirements for maintenance of that license, and
3 usually it is somewhere between twelve to fifteen
4 hours of continuing medication -- continuing
5 education each year. So State Board of Texas,
6 basically, said you had to have, if I remember
7 correctly, thirty hours over a two-year period.
8 Colorado required, I believe, it was twelve hours
9 per year, so it had to be done within the year.

10 And then each state board over time
11 modified, to some extent, what exactly that
12 education had to focus on. So I had usually many
13 more hours of continuing education than necessary
14 to recertify my license.

15 Q. For both Texas and Colorado are there
16 two tiers of licensures; in other words, there's an
17 active if you are practicing versus an inactive
18 that you could maintain?

19 A. I believe there is an inactive
20 status, and technically, I think that is my status
21 with both of those boards.

22 Q. Okay. But up until the dates we were
23 talking about before, 2019 and 2020, you were
24 active and still had to meet these yearly CLE
25 requirements; is that right?

1 A. That is correct.

2 Q. Do you recall taking any continuing
3 education that specifically dealt with a
4 pharmacist's corresponding responsibility?

5 A. I don't.

6 Q. Do you recall taking any continuing
7 education that specifically dealt with the
8 identification of red flags for opioid
9 prescriptions?

10 A. I don't.

11 Q. Do you recall any continuing
12 education that you took that was specific to
13 opioids in any manner?

14 A. I don't.

15 Q. Going back to your CV, if you want to
16 reference it, since I know we have identified a few
17 inaccuracies: Does your CV accurately list all of
18 your professional memberships? It is the second to
19 last page of Exhibit 2.

20 A. That membership list changes over
21 time, has changed over time. So -- so it doesn't
22 include every organization I have ever belonged to.

23 Let's see. Again, these are pages I
24 visit infrequently, I guess, when I maintain this
25 document. I am no longer an active member of the

1 American Pharmacists Association.

2 Q. When did you stop becoming a member
3 of that association?

4 A. I believe my membership expired in
5 probably December of 2019, but I would have to go
6 back and check my records to ascertain if that is
7 the correct date.

8 Q. Do you recall when you became a
9 member of that association?

10 A. 1986.

11 Q. Is there a reason that you did not
12 renew your licenses for Colorado and for Texas?

13 A. I had no intention of practicing
14 pharmacy again as a pharmacist. My running joke
15 was I was licensed in two states, dangerous in
16 fifty, so I chose not to -- I did not feel
17 comfortable going to practice as a pharmacist.
18 Even though my license was active and I could have,
19 it was not my intention to practice as a
20 pharmacist.

21 Q. Are there any other association
22 memberships that are listed there that you know you
23 no longer belong to?

24 A. No, the rest of them are still
25 current.

1 Q. And are there any other memberships
2 that you recall that are not listed there that you
3 were a member of at one point in time?

4 A. Yes, I was a member of the American
5 Associations of Colleges -- I'm sorry. American
6 College of Clinical Pharmacy, ACCP. I was a member
7 of Academy Health. I am a member -- I guess it is
8 not one that you renew, but I am a member of the
9 pharmacy leadership organization, Phi Lambda Sigma.
10 Those are the ones that come to the top of mind.

11 There might be other organizations I
12 was a member of temporarily over my career, but I
13 don't -- it seems like there was one organization
14 that was only around for a short period of time.
15 It didn't last very long, so obviously, I am not a
16 member of them anymore.

17 Q. I am going to switch to your area of
18 research and your publications. And I know there
19 are quite a few, and we are not going to walk
20 through all of them.

21 But I think it would be helpful if
22 you could have Exhibit 1, which is your report, in
23 front of you and then also have your CV, which is
24 Exhibit 2, handy as well.

25 In general, what would you say has

1 been your primary research focus during your career
2 in academia?

3 A. The safe use of medications.

4 Q. Any medications in particular?

5 A. No, not necessarily.

6 Q. Has your research focused on the use
7 of all types of medications equally?

8 A. Well, you need to qualify equally.
9 My focus is a function of the degree of harm that
10 might be associated with a particular medication.
11 And also my experience as a researcher is also
12 predicated by potential solutions to mitigate that
13 harm.

14 So I haven't focused on all
15 medications equally.

16 Q. Would you agree that over your career
17 your focus has not been on opioids in particular?

18 A. I have contributed to papers that
19 have focused on opioids, but the vast majority of
20 my research has been focused on drug-drug
21 interactions. So -- and which do include opioid
22 medications at times.

23 And I am not sure if that answers
24 your question. So --

25 Q. Okay --

1 A. Would you like to restate.

2 Q. I will. You said that the vast
3 majority of your research has been focused on
4 drug-drug interaction. Would you agree that the
5 vast majority of your research has not been focused
6 on drug-drug interactions involving opioids?

7 A. I'm smiling because there are some
8 drug interactions that do involve opioid
9 medications, yeah. So it is difficult for me to
10 answer your question as phrased because
11 occasionally opioid medications are a component of
12 my research.

13 Is that a fair statement? Does that
14 answer your question?

15 Q. Not -- not quite. Let me try it
16 again. I appreciate that you have occasionally
17 done research on opioid medications as part of
18 drug-drug interactions. But I have read a lot of
19 your material, and the vast majority of it does not
20 seem to mention opioids at all; is that a fair
21 statement?

22 MR. WEINBERGER: Objection --
23 objection as to form, misleading. Assumes facts
24 not in evidence. You can answer.

25 A. I'm sorry, Pete, you broke up there

1 with that last statement.

2 MR. WEINBERGER: Sure. Assumes facts
3 not in evidence.

4 Q. (BY MS. FUMERTON:) I am asking what
5 your research is focused on, and you said the vast
6 majority of your research is focused on drug-drug
7 interaction, correct?

8 A. That is correct.

9 Q. And the vast majority of the
10 drug-drug interactions that you have researched do
11 not involve opioids, correct?

12 MR. WEINBERGER: Objection to form.

13 A. Again, it -- opioids -- so the number
14 of drug interactions that I have focused on is
15 somewhat limited, or limited to those that tend to
16 be associated with harm.

17 And, therefore, you know, of those,
18 you know, opioids constitutes one class of
19 medications that are involved in some of those drug
20 interactions. So the statement "vast" is overly
21 broad. You know, so I can't say -- I can't agree
22 with your statement because the number of drug
23 interactions that are clinically important or
24 relevant is fewer than most people imagine. So we
25 are talking in the neighborhood of twenty-five or

1 thirty different medication combinations that are
2 relevant for my research, and of those twenty-five
3 to thirty, opioids constitutes three or four
4 different combinations.

5 Q. (BY MS. FUMERTON:) So the vast
6 majority of combinations that you research do not
7 involve opioids, correct?

8 MR. WEINBERGER: Objection. Asked
9 and answered. Go ahead. You can answer.

10 A. Opioids are included in my research.
11 My research is not focused specifically on opioids.

12 Q. (BY MS. FUMERTON:) And I am not
13 disputing that you have ever done some research on
14 opioids, but you have been in academia for thirty
15 years. And what I am trying to get a sense of is
16 the extent to which your research has involved
17 opioids.

18 And I think you mentioned that
19 there's twenty-five or thirty drug combinations
20 that are particularly relevant to your research,
21 and only three or four of them are opioids,
22 correct?

23 A. Three or four drug pairs that we
24 focused on, on that, are opioids, that is correct.

25 And, you know, maybe I could -- so

1 the term "vast" is what is hanging me up. When you
2 use that term, I guess I am assuming that you are
3 meaning almost all of my research. And I have
4 exception with that characterization.

5 Q. Would you say ninety percent of your
6 research does not involve opioids?

7 A. As a function of my papers, you know,
8 I can't agree with a specific number, but it is --
9 but it is somewhere in that sense, you know. So it
10 is not every -- you know, my research focus is not
11 opioids per se directly.

12 I --

13 Q. A --

14 A. If I could just qualify that
15 statement.

16 MR. WEINBERGER: Go ahead.

17 Q. (BY MS. FUMERTON:) Sure.

18 A. So I have been involved in research
19 that has looked at opioid use and abuse as a part
20 of a research team, and we have published those
21 papers over the past three years in various
22 journals.

23 So -- so that research, I guess,
24 falls under the notion of opioid-related research.

25 Q. Okay. If we look at your report on

1 Page 1, I am looking at the second full paragraph,
2 you write, "My research career over the past
3 twenty-nine years has been focused on improving
4 medication and patient safety. This work has
5 largely been supported by the Agency For Healthcare
6 Research and Quality (AHRQ)." Is that correct?

7 A. Yes, it is.

8 Q. What percentage of that work that was
9 supported by AHRQ focused on opioids?

10 A. Almost all of my work funded by AHRQ
11 is focused on drug interactions. So back to my
12 previous statements. Drug interactions have been a
13 component of that -- opioids have been a component
14 of the drug interactions I have studied. None of
15 these grants are specific to opioid medication use
16 where I am listed as the principal investigator.
17 However --

18 Q. And in fact, some of those -- go
19 ahead.

20 A. Hang on a second.

21 If you do look at -- so I focused on
22 those grants where I was the principal investigator
23 on the particular research project because those
24 are the grants I am responsible for.

25 If you look on Page 29 of my CV, so I

1 guess Exhibit 2, the top of Page 29, there's a
2 grant that was funded by the National Institute For
3 Drug Abuse where I am a co-investigator, along with
4 other investigators from the University of
5 Pittsburgh, University of Florida, University of
6 Utah and the University of Arizona.

7 Q. Okay. But you have received funding
8 from AHRQ that has been directed to specifically
9 researching other medications that are not opioids,
10 correct?

11 A. That is correct.

12 Q. And AHRQ does have resources -- let
13 me try again, see if I can get the word out.

14 AHRQ has researchers that are focused
15 on opioids, correct?

16 A. That is outside my area of expertise.
17 I don't know what they fund.

18 Q. Okay. But you are not one of the
19 researchers that AHRQ funds that focuses on
20 opioids, right?

21 MR. WEINBERGER: Objection to form.

22 Q. (BY MS. FUMERTON:) I will restate
23 the question.

24 A. As stated previously, my research --
25 I can't answer that question because that is

1 outside my area of expertise.

2 Q. Okay.

3 A. I can tell you what I have been
4 funded to do, but I can't tell you what they have
5 been funded to do.

6 Q. Fair enough. In your report, looking
7 back at that same paragraph for Exhibit 1, after
8 discussing AHRQ, you say you have "also received
9 funding from the Centers for Disease Control and
10 Prevention, various state agencies and also the
11 pharmaceutical industry."

12 Did I read that correctly?

13 A. Uh-huh.

14 Q. Is that an accurate statement?

15 A. Yes, it is.

16 Q. And does your CV, which is Exhibit 2,
17 disclose all instances in which you have received
18 funding from the pharmaceutical industry?

19 A. As an academic and researcher, yes,
20 it does.

21 Q. Have you ever received funding from
22 the pharmaceutical industry in the context outside
23 of your career as an academic and researcher?

24 A. So I have served as a consultant to
25 the pharmaceutical industry, usually related to

1 cost effectiveness and health outcomes research.

2 But those are not, you know, research projects. It
3 is giving advice.

4 Q. Okay.

5 A. So those are not -- those are not
6 listed in my academic CV because those are not, in
7 my opinion, academic activities.

8 Q. So I think at the beginning of the
9 deposition, I asked you if you had ever served as a
10 consultant, if you had ever consulted as an expert
11 before.

12 A. Oh.

13 Q. And you mentioned one particular
14 instance as a plaintiff. So I just want to clarify
15 to make sure that I have gotten the full
16 understanding of your consulting work.

17 A. Oh, my apologies. I thought your
18 question was related to legal activities as an
19 expert.

20 As an expert in general, no, that --
21 I have consulted through the pharmaceutical
22 industry, lots of different organizations over
23 time, professional organizations, National
24 Institutes of Health as an expert reviewer on
25 grants, various entities that -- the Food and Drug

1 Administration, I guess I do have that listed on my
2 CV as more of an academic activity, but I have been
3 paid for those activities.

4 I have been employed as a consultant
5 to review materials or to give advice to various
6 pharmaceutical companies over time and, I guess
7 broader context, you know, different healthcare
8 organizations. So the list is extensive, let's put
9 it that way.

10 Q. Okay. Yeah, I appreciate that
11 clarification, so let me see if I can just narrow
12 it down a little bit. You have listed in your CV a
13 number of instances in which you have consulted
14 with different stakeholders in the pharmaceutical
15 industry, correct?

16 A. In my CV? No, I don't -- I don't
17 list my consulting activities in my CV.

18 Q. Okay. So this is what I am just
19 trying to make sure that we are not talking past
20 each other and I am understanding what you are
21 saying.

22 So you do, though, in your CV, have
23 listed a number of various research and other -- I
24 don't want to put words in your mouth, but what
25 would you describe, I guess, what you have listed

1 on your CV along these lines and what would you
2 describe as not listed on your CV so we can sort of
3 narrow down sort of what we are talking about?

4 A. Funds for research. So activities
5 that support research are listed in my CV. And
6 that includes funds that I have received over the
7 years from various pharmaceutical organizations.

8 What is not listed in my CV are
9 consulting activities that generally do not fall
10 under the term of "research," so they are advising,
11 giving opinion, those activities are not listed in
12 my CV.

13 Q. Okay. You have had a long career.
14 So I am going to try to talk globally, and we can
15 get into specifics.

16 Approximately how many of these
17 consulting activities do you think you have had in
18 your career?

19 A. Oh, it would be challenging to say
20 because they come and go so frequently. Like, you
21 know, probably in the neighborhood of fifty or so.

22 Q. And do you have a separate consulting
23 company that you do this activity through?

24 A. Yes.

25 Q. What is your consulting company?

1 A. Strategic Therapeutics.

2 Q. And how long have you had that
3 company?

4 A. I think since 2004.

5 Q. Is that when you began consulting in
6 this capacity?

7 A. No. I probably started consulting in
8 19 -- probably 1989 -- I'm sorry, 1999 or 2000,
9 somewhere around in there.

10 Q. Okay. All right. So staying with
11 your consulting activity, outside of your academic
12 research, have you consulted for pharmaceutical
13 manufacturers of opioids?

14 A. I believe I attended one meeting in
15 2000 or 2001 -- well, let me clarify that. Yeah,
16 it must have been -- it must have been in 2002,
17 June of 2002, I attended one meeting, and I believe
18 that the sponsor of that meeting was Purdue Pharma.

19 Q. And what was the purpose of your
20 attending that meeting?

21 A. They were -- it was an advisory
22 board, so there were probably fifteen different
23 advisors besides myself giving them advice on how
24 to conduct health outcomes research.

25 Q. Were you paid for that?

1 A. Yes, I was.

2 Q. How much?

3 A. I don't recall.

4 Q. More than ten thousand dollars?

5 A. No.

6 Q. More than one thousand dollars?

7 A. Probably, but I don't recall.

8 Q. Do you recall the specific issue that
9 you were advising them on?

10 A. No, I do not.

11 Q. Do you recall issuing any paper or
12 creating any work product as part of that?

13 A. No, we did not -- or I did not.

14 Q. Do you recall who else made up that
15 advisory board?

16 A. I recall some of the other
17 participants, but I don't recall all.

18 Q. What other participants do you
19 recall?

20 A. Ray Townsend was one of the
21 participants. Sean Sullivan was another
22 participant. And those are two individuals that I
23 just know through my training and just being in the
24 field. Those are the ones that I can definitely
25 identify off the top of my head.

1 Q. Okay. Have you ever -- other than
2 that one meeting, have you ever consulted for a
3 pharmaceutical manufacturer of opioids?

4 A. Oh, I would assume so, given that
5 manufacturers tend to make multiple products. So
6 Johnson & Johnson -- I have consulted for Johnson &
7 Johnson. I believe they do have opioid products.
8 My consulting activities have not focused on opioid
9 products per se.

10 Q. Do you have an approximate sense of
11 how much money you have made from consulting for
12 pharmaceutical manufacturers?

13 A. Collectively?

14 Q. Yes.

15 A. It has been a long time. So it is in
16 the neighborhood of -- my guess is somewhere
17 between twenty-five thousand dollars a year to
18 forty thousand dollars a year on average over the,
19 you know, majority of my career.

20 Q. And that is specific to
21 pharmaceutical manufacturers; is that right?

22 A. Oh, no. No. That would include all
23 organizations, I guess.

24 Q. Okay.

25 A. So included in that might be, you

1 know, serving -- helping out a health plan or a
2 nonpharmaceutical manufacturer. So --

3 Q. Is the majority of the work that you
4 do for consulting for pharmaceutical manufacturers?

5 A. I think that is a fair statement,
6 yes.

7 Q. Do you recall any other instances in
8 which your consulting involved opioids
9 specifically?

10 A. No.

11 Q. Have you ever consulted for a
12 pharmacy company? And let me ask a better
13 question. Have you ever consulted for a retail
14 chain pharmacy?

15 A. None comes to mind at the moment, but
16 I guess I would have to go back through my records
17 to determine if that is accurate.

18 Q. What about a --

19 A. I can --

20 Q. Go ahead.

21 A. I have just done so many activities,
22 been asked to participate in various activities
23 over the course of my career. I just can't recall
24 them all off the top of my head.

25 Q. Do you recall whether you consulted

1 for any independent pharmacies?

2 A. I -- no, I have not, no.

3 Q. What about drug distributors, have
4 you ever consulted for a drug distributor?

5 A. Not to my recollection. You are
6 talking drug wholesaler?

7 Q. Yes.

8 A. Is that what you mean by distributor?
9 Yeah, I don't recall -- well, okay. So here is a
10 fine line. Some of the -- I think
11 AmerisourceBergen owns a group called Ascendant.
12 Ascendant does consulting for the industry. So I
13 have advised Ascendant. So I guess indirectly
14 there's a relationship there.

15 Q. Has your work or your consultation
16 with Ascendant involved opioids?

17 A. I don't recall it involving opioids,
18 no.

19 Q. Okay. I am going to go back to where
20 I started on this before I got a little bit off
21 track, but I am glad we cleared that up.

22 Does your CV disclose all instances
23 of funding for research purposes that you have
24 received from the pharmaceutical industry?

25 A. It discloses all research funding

1 that has been given to a university entity. So as
2 far as I know. And the reason I am hedging this is
3 because when you say "research funding," I may have
4 served as a consultant on a project that was funded
5 to another university or group where I advised,
6 consulted with that research activity.

7 Q. Okay. Have you ever received funding
8 from Endo Pharmaceuticals, to your knowledge?

9 MR. WEINBERGER: From who? I'm
10 sorry. I didn't hear it.

11 Q. (BY MS. FUMERTON:) Endo
12 Pharmaceuticals.

13 MR. WEINBERGER: Okay.

14 A. I don't recall. So the answer is --
15 I don't believe so.

16 Q. (BY MS. FUMERTON:) Are you familiar
17 with the phrase "HOPE field scientists"?

18 A. If you mean health outcomes liaison
19 scientists or health outcomes and pharmacoeconomics
20 liaison, then, yes, I am familiar with that.

21 Q. What about HOPE, standing for Health
22 Outcomes and Pharmacoeconomics?

23 A. At the University of Arizona, there's
24 a center called Center For Health Outcomes and
25 Pharmacoeconomics Research. So -- so HOPE could

1 represent a number of different, I guess,
2 activities or organizations or individuals,
3 depending upon the context that that is used.

4 Q. Can you pull out Tab 6 and 7 from
5 your book or from your box?

6 A. Okay.

7 MS. FUMERTON: And I am going to mark
8 these collectively as -- what are we on, Exhibit 4?

9 THE REPORTER: Yes.

10 MS. ZINMASTER: That is what we are
11 on, yes, Tara.

12 MR. WEINBERGER: Tara, you said 6 and
13 7?

14 MS. FUMERTON: Yes.

15 (Exhibit 4 was marked for
16 identification.)

17 Q. (BY MS. FUMERTON:) Now, while you
18 are doing that, Dr. Malone, just for the record,
19 Exhibit 4 is an email and attachment with a Bates
20 number starting ENDO-OPIOID_MDL-06622037.

21 A. I am sorry. Could you please repeat?

22 Q. Yeah. I was just saying for the
23 record, so that the document can be identified,
24 what the Bates number is. That is that little
25 imprint at the very bottom right-hand corner, so I

1 wasn't asking you a question about it yet. Please
2 take your time to look at the document.

3 I will represent that you are not on
4 this email at all, and so I don't anticipate
5 necessarily that you would have seen this document
6 before, but I want to ask some questions about
7 that.

8 So just back for the record, again,
9 this is Exhibit 4. It is an email and attachment.
10 The attachment ends in 2038. It is an Excel
11 spreadsheet. And it is from Kent Summers to Kevin
12 O'Brien copying some folks, dated August 9th, 2012.

13 And Dr. Malone, please take the time
14 to review the document. I am going to ask you
15 about a particular portion of this spreadsheet that
16 I think we can help -- just one line of it
17 actually. But --

18 MR. WEINBERGER: This is -- both of
19 these documents -- excuse me. So you have
20 marked -- so these two documents combined are
21 Exhibit 4?

22 MS. FUMERTON: Yes. It is the email
23 and attachment.

24 MR. WEINBERGER: So in my -- in my
25 envelope -- Ms. Fumerton --

1 MS. ZINMASTER: Mr. Weinberger, what
2 is Tab 7 is an Excel spreadsheet. And to the
3 extent we couldn't authenticate the printout of the
4 Excel spreadsheet, we included it on a thumb drive
5 in case we ended up with a disagreement there. But
6 the document that is Tab 7 that we have marked as
7 part of Exhibit 4 is an Excel spreadsheet that
8 native is on that disk.

9 MR. WEINBERGER: Okay. Thank you.

10 MS. FUMERTON: I see this is not
11 going to be an issue because I am just going to
12 have some questions to see if it refreshes his
13 recollection about something. I'm not going to ask
14 him to authenticate the spreadsheet unless he has
15 seen it.

16 Q. (BY MS. FUMERTON:) Dr. Malone, have
17 you --

18 MR. WEINBERGER: You have totally
19 confused me, but I am easily confused so -- all
20 right. Go ahead.

21 Q. (BY MS. FUMERTON:) Follow along, I
22 am -- Dr. Malone, you have taken a second to
23 review. Are you ready for me to ask a couple of
24 questions?

25 A. Yeah, please go ahead.

1 Q. I will start with the first one.
2 Have you ever seen this email or attachment before?

3 A. No.

4 Q. Okay. I will represent that it was
5 produced in the MDL litigation. Do you know who
6 Kent Summers is or Kevin O'Brien? That is the
7 individuals that are at the primary two lines at
8 the top of the email.

9 A. I do know Kent at least -- yeah, I
10 know Kent. I have met so many people over my
11 career, I don't recall Kevin directly.

12 Q. Okay. And how do you know Kent?

13 A. We have been in the same field of
14 research. So I mean that extends -- health
15 outcomes research. So his doctoral degree is
16 similar to mine, yeah. And I have --

17 Q. And --

18 A. And I was asked to review
19 Dr. Summers' promotion packet when he was going up
20 for promotion when he was at University.

21 Q. Okay. And Dr. Summers appears, at
22 least on this email, to be the vice president of
23 Health Outcomes and Pharmacoeconomics, Clinical
24 Development and Medical Sciences for Endo Health
25 Solutions. Is that how you know him?

1 A. No, I knew him before that.

2 Q. Let me ask a better question. Yeah,
3 I apologize, that was a poor question.

4 Were you aware that he worked for
5 Endo Health Solutions at one point?

6 A. Yes, I was.

7 Q. Okay. And if you look down below,
8 there's another email from Tim Birner to
9 Mr. Summers or Dr. Summers. I can't recall, did
10 you say whether or not you knew Tim Birner?

11 A. I believe I had met the gentleman.
12 Again, it is not somebody I worked with or have
13 knowledge of working with. Again, I --

14 Q. And --

15 A. I'm sorry. I cut you off.

16 Q. No. No. No. I need to count to two
17 before I ask a question so I am not cutting you
18 off. It is my fault.

19 The subject line at the bottom email
20 says "a hundred forty-one examples of supporting
21 OPANA® for the HOPE field scientists."

22 Do you see that?

23 A. Uh-huh.

24 Q. Does that refresh your recollection
25 as to what a HOPE field scientist is?

1 A. Yes, it does. How they are using --

2 Q. What is a HOPE field scientist?

3 A. So the broad area of Health Outcomes
4 and Pharmacoeconomic Research incorporates the
5 effectiveness, the costs, the adverse events, side
6 effects, patient-reported outcomes. So it is a
7 very broad field that is used in the
8 pharmaceutical -- by the pharmaceutical industry
9 and those of us who do research in this general --
10 in the general area of health outcomes to represent
11 a fairly diverse group of disciplines, let's put it
12 that way.

13 Q. Were you a HOPE field scientist?

14 A. No. Well, I am sorry. Was I -- so
15 when you say "HOPE field," that means -- in my
16 opinion, HOPE field basically -- a field scientist
17 is somebody that represents a company, a
18 pharmaceutical company that is not based at the
19 primary organization's location. So these are
20 individuals that are employed in different
21 geographic locations than the primary place of
22 business.

23 So many pharmaceutical companies
24 employ these individuals. Usually they are
25 healthcare professionals, they are either

1 physicians, pharmacists, may have a Ph.D., and
2 their goal is to provide information to the
3 community at large, mainly -- when I say "community
4 at large," usually managed care organizations,
5 physicians, other learned professionals, and also
6 to gather information and bring it back to the
7 organization for designing future research or
8 engagement activities.

9 Q. Okay. Can I -- so I appreciate the
10 explanation, but going back to my question, I'm not
11 sure I know what the answer is now.

12 Were you a HOPE field scientist?

13 A. I was never employed by a
14 pharmaceutical company. So, no, I was not a HOPE
15 field scientist.

16 Q. So if you look at the second email on
17 the first page of Exhibit 4, so the bottom email,
18 Tim Birner appears to be writing to Kent Summers
19 and says, "Morning, Kent. After our discussion
20 about transparency last week, I asked the field
21 team to provide me with a list of current
22 opportunities/efforts related to OPANA®. Attached
23 is a list of one hundred forty-one specific ways
24 the field HOPE team is engaged with customers to
25 support OPANA®." Do you see that?

1 A. Uh-huh. Yes, I do.

2 Q. Were you ever engaged with customers
3 to support OPANA®?

4 MR. WEINBERGER: Objection to the
5 form.

6 A. I'm not sure what you mean by
7 "engaged." Did they ever talk to me about their
8 research? Probably. Did I actually do research
9 for them? No.

10 Q. (BY MS. FUMERTON:) Okay. If you can
11 look to the attached spreadsheet, then, I am going
12 to draw your attention to the second page. And
13 about halfway down the page, you will see listed as
14 Dan Malone, University of Arizona.

15 A. Uh-huh.

16 Q. And under the column of "Strategy,"
17 it appears this says, "Collaborative author on
18 manuscripts using research by Health Analytics
19 4Q11, regarding the management and decisions made
20 by health plans and PBMs to manage DDI,
21 specifically focusing on CYP."

22 Sir, is that right?

23 A. I believe that is what it says, yes.

24 Q. Are you the Dan Malone that is
25 referenced there?

1 A. I am.

2 Q. Okay. And so Endo is describing the
3 spreadsheet that you are on as a list of a hundred
4 forty-one specific ways that the Field HOPE team is
5 engaged with customers to support OPANA®, right?

6 MR. WEINBERGER: Objection to form.
7 Assumes facts not in evidence. Speculative. Go
8 ahead. You can answer.

9 A. Based upon what they wrote, so --
10 yeah, I can't comment on what their intent was with
11 that email.

12 Q. (BY MS. FUMERTON:) I am not asking
13 what their intent was. But what I am asking is why
14 are you listed on this spreadsheet, to cut to the
15 chase. Do you know?

16 A. So I --

17 MR. WEINBERGER: Objection. So wait,
18 wait. Let me object. Wait, let me object. I'm
19 sorry. Objection. You did make certain
20 assumptions. This is a document that he obviously
21 has -- was not a part of nor has he ever seen
22 before. And so I am objecting as to form and that
23 it assumes evidence -- or facts not in evidence.
24 Go ahead.

25 MS. FUMERTON: Well, I've been

1 waiting to say this to you: I object to your
2 speaking objections and coaching of the witness.
3 So just say "objection to the form," and that is
4 sufficient.

5 MR. WEINBERGER: Well, do you want to
6 go back over your transcript?

7 MS. FUMERTON: Well, I --

8 MR. WEINBERGER: Wait. Wait. Wait.
9 Wait, please. Do you want to go back over the many
10 deposition transcripts where you have interposed
11 objections way beyond objections as to form? Do
12 you want to do that?

13 Because there's a litany of those
14 kinds of objections and statements on the record in
15 just the few depositions that you and I have
16 participated in. So I am going to object as I feel
17 appropriate. Thank you.

18 Q. (BY MS. FUMERTON:) Dr. Malone, can
19 you answer the question? We can have the court
20 reporter read it back if you don't remember what it
21 is at this point.

22 A. That would be helpful. Thank you.

23 THE REPORTER: One moment.

24 (Record read.)

25 A. So the reason I think my name is

1 there is I do recall a meeting with Kent and one of
2 their individuals in -- I guess -- I don't know
3 about the specific dates. I met with so many
4 people over so many years.

5 But I do recall them coming to my
6 office while I was employed at the University of
7 Arizona and talking about my research related to
8 drug interactions. And they had, I guess -- their
9 goal was to engage me in some of their activities.
10 I don't recall it -- it manifesting in much, but
11 again, I have done so many activities over time, I
12 don't recall the specifics.

13 Q. (BY MS. FUMERTON:) Looking at the
14 spreadsheet, it says, "Collaborative author on
15 manuscript, using research for Health Analytics
16 4Q11, regarding the management and decisions made
17 by health plans and PBM to manage DDI, specifically
18 focusing on CYP." Do you know what "collaborative
19 author on manuscript" is referring to?

20 MR. WEINBERGER: Objection, form.

21 A. I think they wanted to engage me to
22 participate in a -- a manuscript that they were
23 working on at the time.

24 Q. (BY MS. FUMERTON:) Do you recall
25 what the subject matter of that manuscript was?

1 A. Beyond what is written on that page,
2 I don't recall. I don't know if this manuscript
3 ever went anywhere or if it was even written. I
4 would have to go back and look at my files, and
5 quite frankly, I don't know if I have files on
6 this.

7 Q. And the last portion of that entry
8 says, "specifically focusing on CYP." Do you see
9 that?

10 A. Uh-huh.

11 Q. What is that referring to, if you
12 know?

13 MR. WEINBERGER: Objection to the
14 form.

15 A. So CYP is a common abbreviation for
16 Cytochrome P450. It is an enzyme that metabolizes
17 drugs. There's multiple variants of Cytochrome
18 P450.

19 And medications such as oxycodone,
20 and other medications are metabolized via this
21 enzyme. Many -- I won't say all drugs, but most
22 drugs are metabolized to some extent by variants of
23 Cytochrome P450.

24 Q. (BY MS. FUMERTON:) Does that give
25 you -- refresh your recollection at all about what

1 you might have been engaged with Endo about?

2 A. No, it does not. I mean my research,
3 you know, includes drug interactions and, again,
4 all of them have some variants of Cytochrome P450.
5 Obviously, my lack of recollection with regards to
6 this tells me that it was -- that it was one of the
7 many conversations that I have with organizations
8 that come through wanting to engage me, and most of
9 which never lead to any fruitful activities or
10 interesting findings, unremarkable to me.

11 Q. Did you ever do any work in
12 connection with Endo in the Pharmacy Quality
13 Alliance?

14 A. Not to my recollection. Pharmacy
15 Quality Alliance is an organization that is
16 probably supported by -- well, it is supported by
17 the pharmaceutical industry. So the question is
18 rather broad, so I would imagine -- but I haven't
19 received funds from the Pharmacy Quality Alliance
20 to do my research.

21 Q. And after talking about all this,
22 does this refresh your recollection at all about
23 whether you have received funds from Endo related
24 to OPANA®?

25 MR. WEINBERGER: Objection, form.

1 A. I don't recall. With respect to
2 Pharmacy Quality Alliance, we provided -- when I
3 say "we," my research group, had come up with a
4 list of medications that Pharmacy Quality
5 Alliance -- a list of -- I'm sorry, drug
6 interactions, medications involved with drug
7 interactions that the Pharmacy Quality Alliance
8 subsequently adopted and used as a quality
9 measure -- I shouldn't say as a quality measure --
10 as a potential quality measure.

11 But beyond that, you are -- the
12 threads that are there are relatively thin. I
13 don't recall the specifics of this activity
14 beyond -- beyond what I am seeing on the screen.

15 Q. Did you ever receive any funding for
16 research from a pharmacy that dispenses opioids?

17 A. For research, no, not that I can
18 recall.

19 Q. What about for something other than
20 research?

21 A. Pharmacy is pretty broad, so that
22 would include pharmacy chains. And I am not
23 recalling any off the top of my head. Nothing
24 stands out.

25 Q. Going back to your report, and I am

1 looking at Page 1, third sentence, it states, "The
2 balance of my research has been federally
3 supported." When you refer to the "balance of your
4 research," what do you -- what do you mean there?

5 A. The balance of funds to support my
6 research.

7 Q. I guess I am asking what you mean by
8 "balance." Do you mean the majority?

9 A. Oh, definitely, yeah. Definitely the
10 majority.

11 Q. Okay. And you say, "Starting in 2001
12 with the Arizona Center for Education and Research
13 on Therapeutics, A-Z-C-E-R-T." Is that -- do you
14 refer to it that way, do you refer to it as AzCERT,
15 or how do you refer to that acronym?

16 A. AzCERT.

17 Q. So I am not going to remember this.
18 AzCERT, is that right?

19 A. The state abbreviation, A-Z as in
20 Arizona.

21 Q. Oh, AzCERT?

22 A. There you go.

23 Q. Okay. And you say, reading on in
24 that sentence, "the principal focus on preventing
25 drug-drug interactions," and we have talked about

1 that at length some already, correct?

2 I just want to clarify a few things.
3 AzCERT refers to the Arizona Center for Education
4 and Research on Therapeutics, correct?

5 A. That is correct.

6 Q. And are you still involved with
7 AzCERT today?

8 A. Yes. It is -- at the time starting
9 in 2001, it was housed at the University of
10 Arizona. It is no longer housed within the
11 University of Arizona, but, yes, I am.

12 Q. Where is it housed now?

13 A. It is its own entity. It is a
14 nonprofit organization.

15 Q. Is that nonprofit crediblemeds.org?

16 A. That is correct. Well, Credible Meds
17 is part -- Credible Meds is part of AzCERT.

18 Q. Okay. So AzCERT is a nonprofit
19 organization; is that correct?

20 A. Yes.

21 Q. And Credible Meds is a subset of
22 that?

23 A. As far as I understand, yes.

24 Q. Okay. Does AzCERT maintain a
25 website, to your knowledge?

1 A. Yes.

2 Q. And is that website named
3 crediblemeds.org?

4 A. Yes. Well, that is one website.
5 They might have others, but that is the one I am
6 most familiar with.

7 Q. And that came into existence in 2014,
8 about. Is that right?

9 A. Yeah, that was about the -- that was
10 about the time that the principal investigator left
11 the University of Arizona and created this -- took
12 the entity, I guess, outside of the University
13 setting, created the nonprofit organization. So
14 that sounds about right.

15 Q. Do you agree that Credible Meds is
16 best known for its QT drugs list of drugs that have
17 a risk of QT prolongation and cardiac arrhythmia?

18 A. Yes.

19 Q. And what is QT prolongation?

20 A. It is a cardiac -- so in the
21 electrical signal in the cardiac muscle, there are
22 different waves of electric signal that occur. QT
23 represents the Q-wave and the T-wave. QT
24 prolongation is the notion of time, the distance
25 between those two different waves occurring. Those

1 are important from the standpoint of if that time
2 is too long, the repolarization, it doesn't occur
3 in a proper sequence, leading to an arrhythmia, and
4 the arrhythmia can result in death.

5 Q. And you have done a lot of research
6 on QT drugs, correct?

7 A. They have been one of the components
8 of drugs that I have studied, yes.

9 Q. But not just one of the components.
10 I mean you have done a significant amount of
11 research on QT drugs, correct?

12 A. I will agree with your
13 characterization, yes.

14 Q. Okay. And opioids are not a QT drug,
15 correct?

16 A. I would have to go back and look.
17 There are hundreds of drugs that are listed on the
18 QT as known or possibly caused QTc prolongation.
19 They are not -- opioid medications are not the --
20 on the known risk list. Whether they are on the
21 possible or probable list, I would have to check.

22 Q. You don't know, correct?

23 A. Off the top of my head, no.

24 Q. Okay. And so AzCERT, or either
25 itself or through Credible Meds, provides paid

1 products for healthcare providers and systems to
2 utilize, correct?

3 THE REPORTER: I'm sorry. I can't
4 hear you. "Provides" --

5 MS. FUMERTON: I'm sorry. I will
6 move closer. I was coming -- far away. Let me
7 just reask the question because it was a poor
8 question too.

9 Q. (BY MS. FUMERTON:) AzCERT provides
10 paid products for healthcare providers to utilize,
11 correct?

12 A. Paid products? No, they are free.

13 Q. Okay. So I am specifically thinking
14 of QT drugs. Is that a product that AzCERT
15 provides?

16 A. A listing of medications that have
17 been associated with QT prolongation, yes, they
18 maintain that list.

19 Q. And Med Safety Scan?

20 A. That is -- it is one of their
21 products, yes.

22 Q. And are you involved with those
23 products in any capacity?

24 A. By default, my research is based on
25 some of those medications, yes. And I am also a

1 volunteer member of the board of directors for
2 Credible Meds.

3 Q. What other boards do you sit on?

4 A. None.

5 Q. Are they listed in your CV?

6 A. No. No.

7 Q. The only board you sit on is Credible
8 Meds?

9 A. The only board I am on at the current
10 time, yes.

11 Q. What about in the past, have you sat
12 on any other boards?

13 A. I sat on a board for the Academy of
14 Managed Care Pharmacy at one point in time as a --
15 they had a spinoff organization that the name -- it
16 was an educational entity that AMCP created, asked
17 me to be on that board. I was also on the board of
18 directors for the International Society for
19 Pharmacoeconomics and Outcomes Research.

20 Q. Okay.

21 A. I was also president of that
22 organization.

23 Q. If we go back to your report on Page
24 1, continuing where we left off, sort of the top
25 two-thirds of the second paragraph, you write

1 "Within the AzCERT I led multiple investigations to
2 evaluate health system issues concerning preventing
3 drug interactions from 2001 to 2011." Did I read
4 that accurately?

5 A. Yes.

6 Q. And is that a true statement?

7 A. Yes.

8 Q. And did any of those investigations
9 specifically involve opioids?

10 A. I believe so. One of the --
11 methadone, I guess I will put it in the broad
12 category, opioid-like medications. It is known to
13 prolong QTc interval, so --

14 Q. Other than methadone, was there any
15 opioids?

16 A. I don't recall off the top of my
17 head.

18 Q. Do you know what scheduled methadone
19 is, the DEA scheduled drug?

20 A. I should know. If I was a
21 pharmacist, I would know. But I haven't kept up
22 with it. I imagine it is probably -- well, it is
23 either a Schedule I or Schedule II, and I am
24 assuming it is probably Schedule II since it is
25 available.

1 MR. WEINBERGER: So can I just
2 interrupt? Is this a good time to --

3 MS. FUMERTON: Sure.

4 MR. WEINBERGER: It is --

5 MS. FUMERTON: Yeah.

6 MR. WEINBERGER: It is 1:08 Eastern
7 Time.

8 MS. FUMERTON: Yeah, let's go off the
9 record.

10 THE VIDEOGRAPHER: Okay. We are off
11 the record at 1:08.

12 (Whereupon, a break was had from 1:08
13 p.m. until 1:23 p.m. EDT)

14 THE VIDEOGRAPHER: We are back on the
15 record at 1:23.

16 Q. (BY MS. FUMERTON:) Dr. Malone, do
17 you maintain a CV that you use for consulting
18 purposes?

19 A. I do not, no.

20 Q. So if you are sort of pitching your
21 services to a pharmaceutical manufacturer, for
22 example, do you provide them with any sort of
23 written materials?

24 MR. WEINBERGER: Objection, form.

25 A. No, I don't. I don't.

1 Q. (BY MS. FUMERTON:) Do you have --

2 A. I don't solicit services directly.
3 They usually contact me.

4 Q. Okay.

5 A. We don't advertise our services.

6 Q. Do you have -- do you have a list of
7 consulting engagements that you have been involved
8 with through Strategic Therapeutics?

9 MR. WEINBERGER: Objection to form.

10 A. No, I don't. No, I don't.

11 Q. (BY MS. FUMERTON:) If you wanted a
12 list of all the consulting engagements that you
13 have had, how would you put that together?

14 MR. WEINBERGER: Objection, form.

15 A. I would have to go back and look at
16 income statements or financial records in order to
17 determine that.

18 Q. (BY MS. FUMERTON:) Does Strategic
19 Therapeutic maintain financial records showing what
20 entities pays you funds?

21 MR. WEINBERGER: Objection to form.

22 A. Yes, it does.

23 Q. (BY MS. FUMERTON:) Going back to
24 your report, I want to talk about a conference
25 grant that was supported by AHRQ, and I am

1 specifically looking about, again, a little over
2 halfway through the -- or a little less than
3 halfway through the second paragraph where it says
4 "building the" -- I think that's just a typo, I
5 think it is supposed to be "building on that
6 success."

7 Do you see that?

8 MS. FUMERTON: Kristin, can we pull
9 it up. Maybe he is having trouble locating it.

10 MS. ZINMASTER: Sorry about that.
11 Just a moment.

12 Q. (BY MS. FUMERTON:) If you can put up
13 the rest of it -- yeah, it's Page 1 of the report
14 and sort of a little above the -- halfway through
15 the second paragraph, above the second -- midway
16 through the second paragraph. I don't know a less
17 confusing way to find it.

18 A. I found it.

19 Q. But I am looking at the sentence that
20 says "building." "Building" -- and I think it was
21 supposed to read "on that success, I led a large
22 conference grant supported by AHRQ," and then
23 there's a series of numbers which read
24 1R13HS021826. And then it says, in parentheses,
25 "PI: Malone," correct?

1 A. Yes.

2 Q. And that number is referring to a
3 grant number; is that right?

4 A. Correct.

5 Q. And this large conference grant
6 supported by AHRQ was "to develop standards for
7 drug interactions, evaluations, classification and
8 communication for clinical decision support
9 systems." Did I read that correctly?

10 A. Yes.

11 Q. Did you develop any standards as part
12 of that activity described there for opioid drug
13 interactions?

14 A. Yes, we did. And I --

15 Q. What are those standards?

16 A. I would say we published three papers
17 that resulted in that conference. So my use of the
18 term "standards" here, I guess would fall also
19 under the rubric of recommendations for best
20 practices. So not technical standards in that they
21 weren't adopted by a standard-setting organization,
22 but these were recommendations for these three
23 components: Evaluation, classification and
24 communication of drug interaction information used
25 within decision support systems.

1 Q. Okay. Do you recall specifically
2 what your best practices were with respect to
3 opioids that you developed?

4 A. This particular research focused on
5 drug interactions. It did not focus on opioids, so
6 I don't necessarily understand your question. Drug
7 interaction.

8 Q. So I asked the question did you
9 develop any standards as part of that activity
10 described there for opioid drug interactions, and
11 you said yes, we did.

12 A. Oh, I'm sorry. I misheard. It
13 wasn't -- we didn't develop opioid standards. I
14 did not hear the word "opioid" in answering your
15 question.

16 Q. Thank you for that clarification.

17 A. Yeah, my apology.

18 Q. So I think the answer to my question
19 then, just if I would repeat it, with respect to
20 this grant and your research, you did not develop
21 any standards for opioid drug interactions,
22 correct?

23 A. So opioids could be a part of those
24 drug interactions, but it wasn't specific to
25 opioids.

1 Q. So to the extent it applies generally
2 to all medications, opioids are a medication, it
3 would have applied. But the research was not
4 specific to opioid drug interactions, correct?

5 A. That is correct.

6 Q. So piecing these things together, so
7 tell me if I am wrong, so on your CV, this grant is
8 listed as "Drug-Drug Interaction, Clinical Decision
9 Support Conference Series." Is that right?

10 Let me see if I can point you to a
11 particular page. Specifically I am looking at Page
12 29 of your CV.

13 A. That is correct.

14 Q. And was that a series of conferences?

15 A. Yes, it was.

16 Q. And do you recall whether opioids
17 were specifically discussed at those conferences?

18 A. I do not.

19 Q. And looking at your CV, Exhibit 2,
20 the amount listed there is two hundred and
21 eighty-seven thousand five hundred and ninety-six
22 plus forty thousand from drug knowledge vendors.

23 Do you see that?

24 A. Uh-huh.

25 Q. And what does the two hundred and

1 eighty-seven thousand five hundred ninety-six
2 number signify?

3 A. That is the amount of support that
4 was provided by the Agency For Healthcare Research
5 and Quality.

6 Q. And you received an additional forty
7 thousand from drug knowledge vendors. Is that
8 right?

9 A. That is correct.

10 Q. And what does drug knowledge vendors
11 refer to?

12 A. Those companies that produce drug
13 knowledge data or information. So those would
14 include First Databank, I believe Multispan --
15 Multispan is the product. I'm not sure if it was
16 them or their parent company that helped support
17 us.

18 Gold Standard is another company that
19 is a drug knowledge vendor. I don't recall whether
20 they contributed to this support or not. It has
21 been a while since I have looked at that.

22 Q. You referred to Multispan. I'm not
23 sure if I am familiar with that.

24 A. Medi-Span.

25 Q. Okay. And you mentioned their parent

1 company -- I want to say parent company, but that
2 might be wrong. But Medi-Span is owned by Wolters
3 Kluwer; is that right?

4 A. As far as I know, yes.

5 Q. And it says "percent effort, five
6 percent." What does that mean?

7 A. That means that that is the amount of
8 support that I used on an annual basis to
9 accomplish these activities. So you could
10 attribute it to, you know, essentially five hours a
11 week or four hours a week.

12 Q. I didn't get enough sleep last night.
13 Can you -- what is the calculation you are doing?

14 A. So basically it is forty hours a week
15 times five percent.

16 Q. Okay.

17 A. So I guess that is eight hours.

18 Q. I see something on your CV, something
19 that is referred to as drug knowledge database
20 vendors -- excuse me. Is that the same thing as
21 drug knowledge vendors?

22 A. It is.

23 Q. So First Databank, Medi-Span, Gold
24 Standard; is that right?

25 A. Correct.

1 Q. Can you pull up what is Tab 12 from
2 the box of materials that we sent you?

3 MR. WEINBERGER: I'm sorry. Which
4 one?

5 MS. FUMERTON: Tab 12.

6 A. I have it.

7 MS. FUMERTON: And for the record, we
8 are marking this as Defendants' Exhibit 5.

9 (Exhibit 5 was marked for
10 identification.)

11 Q. (BY MS. FUMERTON:) And it appears to
12 be a manuscript titled "Recommendations for
13 Selecting Drug-Drug Interactions for Clinical
14 Decision Support." And it is dated April 15th,
15 2016.

16 Dr. Malone, I will give you a second
17 to review this, but I'm not going to ask you about
18 the entirety of it.

19 A. Okay.

20 Q. Dr. Malone, is Exhibit 5 an article
21 that you coauthored?

22 A. Yes, it is.

23 Q. And I didn't count them all up, but
24 there's a number of people listed at the top of
25 that article. Are those all individuals who are

1 also coauthors?

2 A. Yes, they are.

3 Q. And your name is listed last. Does
4 that have any significance?

5 A. It does. I am the senior author on
6 the paper.

7 Q. And what does a senior author
8 signify?

9 A. Usually the senior author is the
10 individual that was responsible for obtaining the
11 funding and providing the overall direction for the
12 research.

13 Q. Does it signify at all your
14 contribution to the written portion of the article?

15 That is a bad question. Let me ask
16 it a different way.

17 Does it signify at all the amount of
18 your involvement in writing the paper?

19 A. Typically, yes, it does.

20 Q. Again, how so?

21 A. The concept for the project is
22 usually developed by the principal investigator of
23 the grant, and, therefore, becomes the senior
24 author on the papers. And they are responsible for
25 the conduct of the grant and all phases of how the

1 grant works.

2 So in this case, this particular
3 paper was supported by that conference grant series
4 that you alluded to a minute ago. So my role as a
5 principal investigator on the grant is to ensure
6 that our work is represented in the public domain,
7 and this is one way of representing that.

8 Q. Okay. And this article is published
9 on April 15th, 2016; is that right?

10 A. It is, yes. That is the date.

11 Q. Okay. So looking at the bottom of
12 the first page of Exhibit 5, there's the abstract.
13 It states, "The purpose is to recommend principles
14 for including drug-drug interactions, DDIs, in
15 clinical decision support."

16 Do you see that?

17 A. I do.

18 Q. And was that the purpose of this
19 paper?

20 A. Yes, it was.

21 Q. On the next page is the Results, Page
22 2 of Exhibit 5. The second to last sentence within
23 Results you write, "We recommend judicious
24 classification of DDIs as contraindicated as only a
25 small set of drug combinations are truly

1 contraindicated." Do you see that?

2 A. I do.

3 Q. Is that statement also true for
4 opioids?

5 A. I'm sorry. I don't understand your
6 question. What do you mean by "also true for
7 opioids"?

8 Q. Well, you said you recommend
9 judicious classification of DDIs as
10 contraindicated. What do you mean by that?

11 A. Oh, okay. The tendency of the
12 editors that produce the drug knowledge, use the
13 term -- in our opinion, use the term
14 "contraindicated" excessively, suggesting that
15 medications could not be used together, you know,
16 in any circumstances.

17 And this recommendation is cautioning
18 against the use of that phrase "Contraindicated,"
19 because in many instances the risk/benefit equation
20 associated with using those medications together
21 overwhelms the risks associated with the drug
22 interactions -- the benefits exceed the risk, and
23 it would make sense to give a combination to the
24 patient, even if there was a risk of a drug
25 interaction.

1 So that applies to any drug
2 interaction, not -- not -- so we are not making it
3 specific to a given medication or medication class.

4 Q. Is it a general statement that you
5 should construe contraindications to be narrow so
6 that you are not having a lot of alerts that need
7 to be overwritten? Is that a fair statement?

8 MR. WEINBERGER: Object to the form.
9 Go ahead.

10 A. That is the -- that is one of the
11 consequences of using a term such as
12 "contraindicated," that you generate an alert and
13 prescribers may view the benefits of the
14 combination to exceed the risks and administer
15 those medications to the patient.

16 Q. (BY MS. FUMERTON:) Because often
17 with lots of types of medications there's a
18 benefits and risk component to it that needs to be
19 weighed, correct?

20 A. I wouldn't say often. I would say
21 every single time, yes.

22 Q. And the focus of this paper is that
23 your findings -- there were a lot of alerts for
24 contraindications where, in fact, the benefits
25 outweighed the risks. So they shouldn't have been

1 contraindications in the first place; is that fair?

2 MR. WEINBERGER: Objection, form.

3 A. The paper or the work group that
4 produced this paper identified examples as part of
5 our discussion where the term "contraindicated" was
6 used and, in our opinion, inappropriately so. So,
7 yes. We suggest a more judicious use of the term
8 "contraindicated."

9 Q. (BY MS. FUMERTON:) And so you would
10 also agree that it would be best practice to use a
11 narrow classification of DDIs as contraindicated
12 when you are looking at opioids and other
13 combinations, correct?

14 MR. WEINBERGER: Objection, form.

15 A. Yes.

16 Q. (BY MS. FUMERTON:) If you go down
17 to, I guess still in that section, the results, it
18 says, "Finally, we recommend more research to
19 identify methods to safely reduce repetitive and
20 less relevant alerts." Did I read that correctly?

21 A. Yes, you did.

22 Q. And why was there a goal to safely
23 reduce repetitive and less relevant alerts?

24 MR. WEINBERGER: Objection, form.

25 A. Clinicians receive many alerts in the

1 course of their interaction with their computer
2 systems. And many of these alerts are not relevant
3 at the time that that alert is generated, based
4 upon either the drug or the patient
5 characteristics.

6 Q. (BY MS. FUMERTON:) And too many
7 alerts result in alert fatigue, correct?

8 MR. WEINBERGER: Objection to the
9 form.

10 A. Yes.

11 Q. (BY MS. FUMERTON:) And what is alert
12 fatigue?

13 A. That is -- I guess I don't have a
14 precise definition of it. But it is the notion
15 that repeated warnings on the same problem would
16 result in an individual kind of tuning out that
17 information, so not paying as close of attention to
18 it as they should when it is truly important. So
19 an alert fatigue --

20 Q. And you --

21 A. Go ahead.

22 Q. No, I am sorry. I didn't -- go
23 ahead.

24 A. And this particular paper is, I
25 guess, attempting to get at the issue of

1 theoretical problems versus, you know, documented,
2 well-established problems associated with drug
3 interactions.

4 Q. Do you agree that reducing alert
5 fatigue improves patient safety?

6 MR. WEINBERGER: Objection, form.

7 A. There's no studies to demonstrate
8 that at this point. That is a scientific premise
9 of many of the activities that we undertake. But
10 as far as I am aware, there have been no studies to
11 document that that relationship holds.

12 But that is the -- in general, the
13 thought that if we reduce alert fatigue, that you
14 will reduce inappropriate overrides.

15 Q. (BY MS. FUMERTON:) And improve
16 patient safety, correct?

17 A. And thereby improve patient safety,
18 yes.

19 Q. And you believe that to be true,
20 correct?

21 A. Yes, it is my scientific premise that
22 that would be a correct interpretation.

23 Q. Do you know if there's a consensus
24 within the medical community as to what set of
25 opioid combinations are truly contraindicated?

1 A. No, I am not.

2 Q. If we look down at Background and
3 Significance section on Page 2, you write that "The
4 contents that the vast majority of DDI decision
5 support systems in the United States is created,
6 maintained and sold by drug knowledge base vendors
7 that use their own approach for evaluating and
8 classifying the clinical importance of DDIs."

9 Did I read that correctly?

10 A. You did, yes.

11 Q. And one of the drug knowledge base
12 vendors that you are referring to there is
13 Medi-Span, correct?

14 A. Yes.

15 Q. And you go on, it says -- skipping
16 one sentence, going to the next one, it says,
17 "Ubiquitous and low clinical relevance alerts have
18 contributed to considerable clinician frustration
19 and dissatisfaction, and reported override rates
20 for DDI alerts consistently exceed ninety percent."

21 Did I read that correctly?

22 A. I believe you did, yes.

23 Q. And that is a problem, correct?

24 A. In my opinion, yes.

25 Q. And why is it a problem?

1 A. It is the relationship between the
2 noise and the signal. There's so much noise that
3 it is very challenging for individuals to pick up
4 the signal. And --

5 Q. So --

6 A. Go ahead. I'm sorry.

7 Q. So if you are flagging ninety percent
8 of a particular medication, for example, that just
9 becomes noise to the person having to evaluate
10 whether or not there truly is an issue, correct?

11 MR. WEINBERGER: Objection, form.

12 A. Yes, I agree with that.

13 Q. (BY MS. FUMERTON:) Do you agree that
14 alert fatigue is more than just a frustration; it
15 can lead to clinicians to respond inappropriately?

16 A. I would generally agree with that
17 statement, that clinicians may, at times --
18 although the evidence heretofore is lacking -- but
19 the general perception of the field, in my opinion,
20 is that alert fatigue does contribute to important
21 signals being missed.

22 And, you know, keeping in mind that
23 all drugs are dangerous if used inappropriately,
24 but in the case of drug interactions, there are
25 certain drug pairs that we probably need to stop

1 and think about whether, you know, these two
2 medications should be used concurrently.

3 And I guess I would just put it in a
4 broader context of any medication that has a high
5 potential for adverse effects, whether there be a
6 drug interaction or any other consequence, adverse
7 event, you know, we want clinicians to slow down
8 and think about the ordering and dispensing of
9 those medications. And I use the term "clinician"
10 fairly broadly, encompassing prescribers and
11 pharmacists.

12 Q. Right. So you believe that alert
13 fatigue can lead to pharmacists responding
14 inappropriately, correct?

15 MR. WEINBERGER: Objection, form.

16 A. There's lots of alerts that
17 pharmacists receive. And, therefore, we would
18 assume that some of those are relevant, some of
19 those are less relevant. And if we could figure
20 out which ones are important, more important, then
21 they would focus their attention on those.

22 And I guess it gets back to this
23 premise that, you know, these medications are
24 dangerous, and, again, if used in the wrong context
25 or in the wrong situation, could result in harm to

1 the patient.

2 So the goal of computers and alerts
3 that are generated -- not just drug interaction but
4 general drug utilization alerts, is to bring to the
5 attention of the practitioner that there is
6 something they need to pay attention to.

7 And the premise of most of this
8 particular paper is that because there are many
9 theoretical nonsubstantiated warnings out there,
10 that those are making it challenging for the
11 prescribers to understand when they need to stop
12 and think -- and pharmacists too -- when they need
13 to stop and think about potential harm that could
14 result in either writing that prescription or
15 dispensing that prescription to a patient.

16 Q. (BY MS. FUMERTON:) The goal is to
17 sort of create an alert system that is as narrow as
18 possible so that the pharmacist, for example,
19 doesn't tune out the noise of all sorts of
20 unnecessary flags, correct?

21 MR. WEINBERGER: Objection to the
22 form.

23 A. As narrow as necessary. I mean you
24 could make an alert system very narrow. So you
25 could turn off alerts, and that is what people have

1 done, they have turned off alerts in some
2 instances, and that provides no benefit at all
3 because now you don't know what you are missing. I
4 think that famous quote was, "We don't know what we
5 don't know."

6 And, you know, so turning off the
7 system is what some organizations have done with
8 respect to drug utilization alerts. And, in fact,
9 it is usually what some organizations do, depending
10 upon the level of the alert, they reduce the alerts
11 because they could perceive them to be irrelevant.

12 That is not the solution that we are
13 recommending. The solution we are recommending is
14 providing the most appropriate warnings to be
15 given, and that needs to be based upon the clinical
16 relevance and the likelihood of harm associated
17 with that.

18 So that is the premise of almost all
19 of my research. It is not that -- we can't just
20 turn all of these off and eliminate alerts.
21 There's just way too much medical information for
22 the clinicians to have to memorize and know in the
23 back of their minds. And that is just humanly
24 impossible. But what we need to do is design
25 systems that bring to the forefront those warnings

1 that need to be paid attention to, and that is the
2 premise of this paper.

3 So I am sorry about that long-winded
4 answer, but that is the focus of much of my
5 research is to identify those situations where it
6 is imperative that we provide that information to a
7 clinician to say don't -- you really want to think
8 about the risk/benefit calculi in this situation
9 because these are dangerous medications that could
10 harm the patient if used inappropriately.

11 Q. (BY MS. FUMERTON:) I just want to be
12 clear. When you are referring to "these
13 medications," you are talking about medications in
14 general, not particularly a particular class of
15 medications?

16 A. Yeah -- I would say that, you know,
17 the FDA is supplying, you know, prescription
18 medications, potentially dangerous medications if
19 used inappropriately. That is why we have a
20 licensed prescriber to use them, right. And then
21 within that, there are groups of medications,
22 depending upon your phylum -- so for drug
23 interactions, there are certain medications for --
24 as we have been talking about for opioids, you
25 know, they are controlled substances, meaning they

1 result in a higher level of standard that needs to
2 be practiced when dealing with those medications.

3 So those -- those kind of notions are
4 embodied in the alerting systems or should be
5 embodied in the alerting systems that are out
6 there.

7 Q. All right. But even with respect to
8 opioids, I think your general premise still holds
9 that the alerts with respect to opioids should be
10 as judicious as possible, in other words, as narrow
11 as possible, because otherwise, the risk/benefit
12 analysis will cause the pharmacist to have alert
13 fatigue?

14 MR. WEINBERGER: Objection, form.

15 A. I -- I can't say "as narrow as
16 possible." It needs to be clinically relevant.
17 Whether that is narrow or not is going to be a
18 function of many factors. It is going to be a
19 function of, you know, what medication is being
20 dispensed, to what type of patient is it being
21 dispensed, under what circumstance is it being
22 dispensed.

23 So we certainly don't want to cry
24 wolf all the time when a patient is not at harm.
25 So dispensing of, you know, a legitimate

1 prescription pursuant to, you know, all of the
2 other criteria that are necessary to dispense a
3 medication, and that includes opioid medications,
4 shouldn't trigger a warning.

5 On the other hand, situations where
6 there's a potential for harm to the patient -- and
7 I keep coming back to this notion of harm. I am
8 putting it under -- I guess you could put lots of
9 things under the notion of harm, but could be
10 mental, physical, economic harm, all of those
11 things, you know, pharmacists or the healthcare
12 system should, you know, limit exposure to harm to
13 the extent possible.

14 Q. (BY MS. FUMERTON:) So let's look
15 some more at Exhibit 5. I am looking at the
16 results, Key Question 1, "What process should be
17 used to develop and maintain a standard set of
18 DDIs?" And I am going to butcher the name,
19 Phansalkar, et al., second sentence?

20 A. Phansalkar, you had it correct.

21 Q. "Identified an initial set of high
22 priority DDIs through an ONC task order that could
23 be used as a minimum standard for electronic health
24 record systems." Did I read that correctly?

25 A. Yes, you did.

1 Q. What is an ONC task order?

2 A. ONC stands for the Office of the
3 National Coordinator. The Office of the National
4 Coordinator is the standard-setting organization
5 under the Department of Health and Human Services
6 that specifies the minimum requirements for
7 effective electronic health systems, which includes
8 use of clinical decision support as it applies to
9 medications. So there's a number of specific
10 statements that this federal agency has promoted to
11 ensure that electronic health record systems are
12 used in accordance with the ultimate outcome of
13 improving patient safety, improving health
14 outcomes.

15 Q. How is an initial set of high
16 priority DDIs identified?

17 A. That particular author created an
18 expert panel and then also used their listing of
19 medications from one particular healthcare system
20 and evaluated various drug combinations to arrive
21 at a number -- a relatively small number of drug
22 interaction pairs.

23 Q. Were opioids included in any of the
24 high priority DDIs?

25 A. I don't recall off the top of my

1 head.

2 Q. Well, does Exhibit 5 tell you the
3 answer to that?

4 MR. WEINBERGER: I'm sorry. I didn't
5 hear the question. What was the question?

6 Q. (BY MS. FUMERTON:) Yeah. My
7 question was does Exhibit 5 tell you the answer to
8 that. So my question was were opioids included in
9 any of the high priority DD developments?

10 MR. WEINBERGER: Understood.

11 MS. FUMERTON: Dr. Malone said he
12 couldn't recall off the top of his head.

13 Q. (BY MS. FUMERTON:) So I guess I
14 would refer you to Exhibit 5 to see if you know the
15 answer?

16 A. You would have to go to Reference
17 Number 23 in order to answer -- I would have to go
18 to Reference 23 to answer your question.

19 Q. And when you say "Reference 23," you
20 are talking about on Page 12?

21 A. The screen has changed, but let me
22 double-check. Oh, yes, it is Page 12, yeah. Thank
23 you.

24 Q. If you turn to the next page --
25 actually I didn't finish reading that sentence, so

1 let's stay on Page 3 for a second.

2 So that individual has "identified an
3 initial set of high priority DDIs through an ONC
4 task order that could be used as a minimum standard
5 for electronic health record systems and a set of
6 DDIs that should be noninterruptive in order to
7 reduce alert fatigue." Did I read that correctly?

8 A. Yes, you did.

9 Q. And what does "noninterruptive in
10 order to reduce alert fatigue" mean?

11 A. It means there's alerts -- let me
12 explain the relationship between an interruptive
13 and noninterruptive, to answer your question.

14 So an interruptive alert is one that
15 requires the recipient of that alert to stop the
16 process of what they are doing and somehow
17 acknowledge that alert. That may be required to
18 check a box, type in letters or, you know, type a
19 response.

20 A noninterruptive alert is
21 information that is presented perhaps on the
22 screen, but it does not inhibit the work flow of
23 the practitioner.

24 So pharmacists or pharmacy technician
25 could continue to process the medication order so

1 it doesn't inhibit the next action, intended
2 action, in the absence of the alert, so the work
3 flow continues.

4 Q. And so, in your view, a
5 noninterruptive alert is preferable to an
6 interruptive alert, correct?

7 A. No, it depends. I'm sorry to
8 disagree with you, but it depends. There are
9 certain situations where you do want to get the
10 attention of the clinician or the pharmacist or the
11 pharmacy personnel and say, listen, this is
12 important that you pay attention to what is
13 happening here.

14 So there are times when you do want
15 to say stop and think about this. There are
16 situations -- you know, other situations where that
17 information is perhaps interesting or nice to know
18 or is less relevant or less likely to cause harm is
19 generally the notion here. So in those situations,
20 you know, you might present the information but not
21 require what we call a click to continue.

22 So when you talk to physicians and
23 pharmacists, you know, the overriding statement is
24 how many clicks does it take me to resolve that
25 problem or to deal with that issue, how many things

1 do I have to do to address that issue.

2 So it is not just alert fatigue, but
3 I guess click fatigue. They don't want to have to
4 check a bunch of boxes for things that are trivial.

5 Q. Okay.

6 A. So --

7 Q. But to go back to looking --

8 MR. WEINBERGER: Excuse me. I think
9 he was finishing his answer.

10 A. And I apologize for the delay. I was
11 going to say, there are situations where
12 medications are -- you need a higher level of
13 attention to the use of that medication.

14 And, you know, the -- in the
15 materials I reviewed, there were situations where
16 they focused on, say, narrow therapeutic index
17 drugs as medications where they had created within
18 their systems, you know, special screens that
19 looked different or brought attention to those
20 medications while they were being dispensed. And
21 so those are -- those are situations -- not just
22 drug interactions, but it applies to lots of
23 different situations where you really want the
24 pharmacists and the pharmacy staff to think about
25 more carefully the situation, the context to which

1 the information -- the drug is being used.

2 And, obviously, with opioid
3 medications as being, you know, part of a closed
4 distribution system, and I guess other medications
5 are used with opioids that, you know, people talk
6 about the trinity notion, muscle relaxants and
7 other products, you know, the goal is to provide
8 information at the time that that information is
9 useful to the clinician, the pharmacists so that
10 they can make the best decision about how that
11 medication can be safely used.

12 So I don't want to diminish the
13 importance of these warnings to the point where all
14 warnings are useless. If we thought that, then we
15 would take away stop signs. So we don't do that.
16 You know, we put stop signs on roads where there
17 needs to be attention by the driver to pay
18 attention to what the cross traffic is.

19 And that applies the same with drug
20 utilization review. There needs to be stop signs
21 when you have potential for the patient, not the
22 pharmacist but the patient to be harmed.

23 Q. (BY MS. FUMERTON:) Okay. Well, I am
24 going to strike the vast majority of that as
25 nonresponsive, which I appreciate your explanation,

1 but we have gone way far afield of what my initial
2 question was.

3 A. Okay.

4 Q. So I want to make sure that the
5 record is clear because I think you trailed off
6 into something completely different.

7 You were talking about these
8 materials that you reviewed. That is not in
9 connection with this article, correct, or are you
10 talking about in connection with these articles --

11 MR. WEINBERGER: Wait, before you
12 answer that question. Are you done, Tara, because
13 I want to interpose an objection?

14 MS. FUMERTON: Sure.

15 MR. WEINBERGER: So I object and move
16 to strike the comments with respect to your
17 comments on his last answer.

18 But go ahead and answer the question.

19 MS. FUMERTON: Would strike your
20 comment, so it will be an endless loop. Let's move
21 on from that.

22 Q. (BY MS. FUMERTON:) So when you were
23 referring to certain materials, what were you
24 referring to? I mean you sort of gave a long
25 answer there. Were you talking about in connection

1 with this article that we were just talking about
2 or something else?

3 MR. WEINBERGER: Objection to form.
4 Go ahead.

5 A. I'm sorry. I was referring to the
6 materials that I was asked to review as a part of
7 this particular litigation.

8 Q. (BY MS. FUMERTON:) So you said that
9 "in the materials I reviewed, there were situations
10 where they focused on, say, narrow therapeutic
11 index drugs as medications where they had created
12 within their system special screens that looked
13 different or brought attention to those medications
14 while they were being dispensed. And so those
15 are -- those are situations, not just drug
16 interactions but applies to lots of different
17 situations where you really want the pharmacists
18 and the pharmacy staff to think about more
19 carefully the situation."

20 So you are not discussing drug-drug
21 interactions in that testimony, correct?

22 A. No. In answer to your -- so I will
23 disagree with your characterization, I am sorry.
24 Drug interactions could be a part of that. The
25 specific example I gave was not a drug interaction.

1 It was a narrow therapeutic situation.

2 Q. Are you saying that you thought that
3 in certain materials you reviewed that you saw
4 there were too narrow of a therapeutic index of
5 drugs as medication?

6 MR. WEINBERGER: Objection to form.

7 A. I am sorry. Perhaps I am using too
8 much health language here.

9 The narrow therapeutic index
10 medications are a class of medications that are
11 inherently more dangerous because they have
12 potential for significant adverse events. The
13 classic example we use is warfarin. Too much
14 warfarin, you bleed; too little warfarin, you clot.
15 So the range to which the warfarin needs to be used
16 is narrow.

17 And one of the defendants in this
18 case produced a document that specifically called
19 out in their electronic system narrow therapeutic
20 index drugs. So warfarin is one example of a
21 narrow therapeutic index drug.

22 Q. (BY MS. FUMERTON:) What defendant
23 are you thinking of and what document are you
24 thinking of?

25 A. If I am correct, it was with respect

1 to Rite Aid, and it was one of the -- one of the
2 documents dealing with their -- I believe they use
3 NextGen computer system.

4 Q. So what is your -- are you offering
5 any opinion about the Rite Aid's NextGen system in
6 your expert report?

7 A. I am just using it as an example as
8 to where an organization has used an extra level of
9 safety as a part of the dispensing process by
10 bringing that to the alert, that information to the
11 forefront of the pharmacist's minds by the way they
12 present the warning.

13 Q. I see. You are using that as an
14 example of a good thing that Rite Aid was doing to
15 alert information to a pharmacist?

16 A. That is correct, yes.

17 Q. Okay. Okay. So going back to sort
18 of this subject of this paper, which I think
19 ultimately the goal was to reduce alert fatigue,
20 right, to create DDI standards that would reduce
21 alert fatigue? Is that a fair summary?

22 MR. WEINBERGER: Objection to the
23 form.

24 A. That is one of the goals, yes. Yeah.
25 Our purpose was --

1 Q. (BY MS. FUMERTON:) And --

2 A. -- not just alert fatigue but, I
3 guess, improving the signal when it was important.

4 Q. Okay. If we go to Page 4, the last
5 sentence of the top paragraph, it says, "This
6 undertaking is not trivial and requires substantial
7 resources."

8 Do you see that?

9 A. I do.

10 Q. And you agree that it is a
11 significant undertaking, correct?

12 A. Yeah, and the context of that needs
13 to be stated because there are thousands of drug
14 interactions promulgated in these drug warning
15 databases, and many of which are not clinically
16 relevant.

17 Because there's over a hundred
18 thousand drug products on the market today, you
19 know, carefully sifting through that evidence and
20 then putting the appropriate level of warning on
21 that evidence for that drug combination is a
22 significant amount of work. So that is what
23 that statement refers to.

24 Q. And you are not offering any opinions
25 in this matter as to what the appropriate level of

1 warning would be for any drug combination involving
2 opioids, correct?

3 A. Restate the question. I'm sorry.

4 Q. Sure. In this litigation and in your
5 expert report, you are not offering any opinions as
6 to what an appropriate level of warning would be
7 for any particular drug combination involving
8 opioids, correct?

9 A. That is correct, no.

10 Q. You are saying there should be a
11 system, but you are not saying what the system
12 specifically should alert?

13 A. That is correct.

14 Q. Fair?

15 And the next paragraph on Page 4, you
16 write, "In light of these issues and ongoing
17 challenges, we recommend forming a national
18 consensus panel of experts to create and maintain a
19 standard set of clinically-relevant DDIs for CDS
20 systems with oversight by a national organization
21 to ensure that the process is transparent,
22 systematic and evidence driven."

23 Do you see that?

24 A. Yes, I do.

25 Q. And you agree with that

1 recommendation?

2 A. Yes, I do.

3 Q. To your knowledge, has that ever
4 happened?

5 A. No. Funding has never resulted in
6 that to occur. And just the -- again, the context
7 matters here.

8 If you were to take First Databank's
9 drug interaction evidence and put it next to
10 Medi-Span's drug interaction evidence, there's a
11 significant number of discrepancies between those
12 two databases. So if a pharmacist worked for one
13 pharmacy organization and used MultiSpan -- excuse
14 me, Medi-Span, and another organization that uses
15 First Databank, they may get entirely different
16 warnings based upon that.

17 Therefore, our intent with that
18 statement was to create a unifying standard of
19 which interactions were important to warn and
20 classification of that by an expert group to reduce
21 the discrepancy across these vendors that provide
22 this information.

23 Q. Right. And in your view, the
24 solution to that is to create this national
25 consensus panel of experts to unify those standards

1 and alerts, technically, correct?

2 A. That's correct, yes.

3 Q. On Page 8 under Question 3, the
4 question is, "Can/should a list of contraindicated
5 drug pairs be established?"

6 THE REPORTER: I can't understand you
7 and I don't see the document.

8 MS. FUMERTON: Sure. I will slow
9 down.

10 Q. (BY MS. FUMERTON:) On Page 8 of
11 Exhibit 5, under Key Question 3, the question is,
12 "Can/should a list of contraindicated drug pairs be
13 established?"

14 And the first sentence, I think,
15 Dr. Malone, is just what you were referring to,
16 that it is important to recognize that there has
17 been inconsistent use of the term "contraindicated"
18 in various drug information sources, correct?

19 A. Yes.

20 Q. "Contraindicated DDIs are those for
21 which no situations have been identified where the
22 benefit of the combination outweighs the risk."
23 You agree with that statement, correct?

24 A. Yes.

25 Q. If we go down to the middle of that

1 page, it says, "Classifying an interaction as
2 'contraindicated' should be done judiciously and
3 perhaps infrequently, as only a small set of drug
4 combinations are absolutely contraindicated."

5 You agree with that statement,
6 correct?

7 A. I do.

8 Q. Are you aware of whether or not there
9 are any opioids combination for which the benefit
10 of the com -- I'm sorry. Let me restate this
11 question.

12 Are you aware of whether or not there
13 are contraindicated DDIs for opioids where there
14 are no situations that have been identified where
15 the benefit of the combination outweighs the risk?

16 If I ask a stupid question, please
17 tell me it is a stupid question because when I am
18 looking at it, I realize it might be.

19 When I use a term, I want to be
20 clear. When you say "contraindicated DDIs," what
21 you are talking about are two -- the combination of
22 two drugs are contraindicated, right?

23 A. Generally speaking, people refer to
24 just two, but could apply to three, yeah.

25 Q. To more?

1 A. Yeah.

2 Q. Are you aware of any drug-drug
3 interactions involving opioids for which there are
4 no situations that have been identified where the
5 benefit of the combination outweighs the risk?

6 A. I'm not aware of any, no.

7 Q. If you go to Page 9 of this article,
8 I am looking at the first full paragraph on Page 9.
9 It says, "Keeping in mind the five 'rights' for
10 health IT medication safety (right information,
11 right person, right CDS format, right channel,
12 right time in work flow), there are situations
13 where DDI notification is repetitive or
14 irrelevant."

15 Did I read that correctly?

16 A. Yes.

17 Q. So it says, "For example, in some
18 systems, DDI alerts may be generated for refills or
19 continuations of existing medications. Changes in
20 dosing, strength, time of administration, and
21 transfer between inpatient units can result in
22 repetitive alerts that contribute to alert fatigue.
23 Some experts advocate the ability to suppress
24 alerts at the time of renewal of
25 previously-tolerated medication combinations for

1 the same patient."

2 Do you see that?

3 A. Yes, I do.

4 Q. Do you agree with suppressing alerts
5 at the time of renewal of previously-tolerated
6 medication combinations involving the same patient?

7 A. It depends. So keep in mind that
8 individuals on this panel included those that work
9 in the inpatient setting where you may move a
10 patient from a higher level of care to a lower
11 level care, and that -- that -- you know, that
12 alert has been presented once and adjudicated by
13 both the prescriber and/or the pharmacist.

14 So -- so there are times when
15 suppression of those warnings is -- is appropriate.

16 Q. Right. So even in the outpatient
17 context, if a pharmacist is presented with a
18 prescription for a particular patient, and they
19 evaluate the circumstances specific to that patient
20 and determine that it is appropriate to fill that
21 medication, then the next time that patient comes
22 in, they can sort of rely on the fact that they
23 have already previously looked at information, sort
24 of cleared any concerns they had when deciding to
25 fill that medication for that patient again?

1 Correct?

2 MR. WEINBERGER: Objection to the
3 form.

4 A. If the -- the context here, again,
5 was more focused on inpatient.

6 In the outpatient setting, I believe
7 that practitioners probably want to interpret the
8 situation that way, but that is not always the
9 case. The patient situation may have changed
10 between the first fill and the second fill.

11 So -- and there are some, you know,
12 warnings that probably don't need to be displayed
13 the second time around, and there are other
14 warnings that might need to be displayed the second
15 time around depending on the situation.

16 So we would have to get into the
17 specific -- we would have to talk about, you know,
18 the patient, the drugs, the type of warning that is
19 being -- you know, would be generated and, you
20 know, the -- I guess external factors, I will just
21 try to put it in a broader context, associated with
22 that medication.

23 So it could be appropriate in
24 situations, and -- or, you know, so it is not a
25 carte blanche. So I just want to be careful about

1 giving that impression.

2 Q. (BY MS. FUMERTON:) Well, and I
3 think, you know, if we keep reading on that
4 sentence, we may get to the point which is, it
5 states, "Patients with long-term use of certain
6 medications may have demonstrated their capacity to
7 tolerate them, and suppressing alerts for refills
8 might be an option for some circumstances,"
9 correct? Do you agree with that statement?

10 A. I agree with that statement, yes. We
11 wrote that.

12 Q. And based on your prior explanation,
13 you also agreed that in order to evaluate whether
14 or not there is a cause for concern, you really
15 have to look at the individual circumstances of
16 that patient, correct?

17 A. That is correct.

18 Q. And so you agree that a particular
19 DDI alert may be intelligently ignored for a
20 specific patient, right?

21 A. That is correct, I agree.

22 Q. So you have -- on your CV, you have
23 listed meaningful drug interaction alerts as one of
24 the grants that you were -- or one of the topics, I
25 guess, for a grant that you received.

1 And I will give you a specific page.

2 A. Excuse me, Tara. So I recognize that
3 it is getting late in the day for some people, or
4 at least past lunchtime for some people. So if
5 there's a desire to break for lunch, maybe this
6 would be the time to do it.

7 MS. FUMERTON: Totally up to you. I
8 will go forever if somebody doesn't stop me, so
9 that is fine. We can go for another half hour. It
10 is totally up to you.

11 MR. WEINBERGER: So why don't we take
12 a break right now. And should we break for, say,
13 forty-five minutes, Dr. Malone?

14 MS. FUMERTON: I was going to suggest
15 thirty just because we had a little bit of a delay
16 earlier, but if that is not enough time for
17 folks -- I mean thirty would be my preference, but
18 it is up to you, again, Dr. Malone --

19 MR. WEINBERGER: So as you can see,
20 Dr. Malone, rarely do Tara and I agree even on some
21 of the more trivial issues. But I say that in just
22 an abundance of humor.

23 So what is your preference? You and
24 the court reporter are the most important people to
25 consider.

1 A. I can do whatever. I am not going
2 anywhere. So -- so I am happy to do --

3 MS. FUMERTON: Let's go off the
4 record.

5 THE VIDEOGRAPHER: Okay. We will go
6 off the record at 2:29.

7 (Whereupon, a break was had from 2:29
8 p.m. until 3:17 p.m. EDT)

9 THE VIDEOGRAPHER: We are back on the
10 record at 3:17.

11 Q. (BY MS. FUMERTON:) Good afternoon,
12 Dr. Malone. You understand you are still under
13 oath, correct?

14 A. I understand that, Ms. Fumerton.
15 Thank you.

16 Q. Can you please grab what has been
17 marked as Tab 10. And while you are doing it, we
18 are also going to be pulling up Tab 11 and Tab 13,
19 if you want to grab those.

20 But we are going to start with Tab
21 10.

22 (Exhibit 6 was marked for
23 identification.)

24 MS. FUMERTON: And so we are going to
25 mark what was Tab 10 as Exhibit 6. And for the

1 record, it is an article titled "Designing and
2 Evaluating Conceptualized Drug-Drug Interaction
3 Algorithms." And it was received on January 29th,
4 2020 and it looks like accepted on March 9th, 2021.

5 Dr. Malone, I will give you a minute
6 to look at this, and let me know when you are ready
7 for some questions.

8 A. Okay. Getting all of the documents
9 together.

10 Q. (BY MS. FUMERTON:) And we are just
11 looking at the Tab 10 first, if that helps. You
12 don't have to pull the other ones out yet.

13 A. Okay.

14 (Pause.)

15 A. Okay. Go ahead.

16 Q. (BY MS. FUMERTON:) So Exhibit 6 is
17 an article titled "Designing and Evaluating and
18 Contextualized Drug-Drug Interaction Algorithms"
19 that you coauthored, correct?

20 A. It is.

21 Q. And your name is listed last, so this
22 is an example where you were a senior author. I
23 apologize. I think I am misremembering the term
24 you used previously.

25 A. That is correct. Senior author.

1 Q. Senior author? Okay. Great. This
2 is another article where you are analyzing how to
3 reduce alert fatigue, correct?

4 A. Yes, it is.

5 Q. And evaluating the appropriateness of
6 alerts, you agree that contextual factors are
7 important, correct?

8 A. Yes, I do.

9 Q. And you also agree that individual
10 patient characteristics are important, correct?

11 A. They can be, yes.

12 Q. In fact, if you look at the abstract,
13 in the third sentence under the objective, it
14 states, "Existing alerting systems for DDIs are
15 often simplistic in nature or do not take the
16 specific patient context into consideration,
17 leading to overly sensitive alerts." Correct?

18 A. It does state that, yes.

19 Q. And you agree with that statement,
20 correct?

21 A. Yes, we wrote that.

22 Q. Well, you wrote it and you agree with
23 it, correct?

24 A. Yes, I do.

25 Q. Okay. In the Results section of the

1 abstract, it talks about how "algorithms and
2 computable knowledge artifacts were developed and
3 validated for a total of eight high priority DDIs."
4 Do you see that?

5 A. Yes, I do.

6 Q. What makes something a high priority
7 DDI?

8 A. The potential for harm. So the
9 likelihood that a patient who experiences these
10 dangerous combinations of medications could be
11 harmed. So the premise of this paper and, in fact,
12 most of my research is identifying situations where
13 patients may be placed at great risk of harm, and
14 that is what we mean by higher priority or
15 clinically-relevant algorithms.

16 Q. And so one of the eight DDIs --
17 strike that.

18 One of the high -- one of the eight
19 high priority DDIs that you looked at involved an
20 opioid, correct?

21 A. I believe so, yes.

22 Q. If you need to reference it, it is on
23 Table 3 on Page 6.

24 And the DDI that you identified with
25 that opioid is Fluconazole? Fluconazole? If you

1 could pronounce it correctly for me.

2 A. Fluconazole.

3 Q. Fluconazole, thank you. So the DDI
4 here is an opioid and Fluconazole. What is a
5 Fluconazole?

6 A. It is an antifungal medication.

7 Q. So you didn't identify as one of the
8 high priority DDIs an opioid and a benzodiazepine,
9 correct?

10 A. No. And --

11 Q. And you didn't identify --

12 MR. WEINBERGER: Wait.

13 MS. FUMERTON: Yes or no question.

14 MR. WEINBERGER: No, no. He was --
15 you interrupted him -- interrupted him. He was in
16 the middle of completing his answer. Please allow
17 him to complete his answer.

18 MS. FUMERTON: Well, it was a yes or
19 no answer -- question and he answered no. But if
20 you want to redirect him, I'm sure that --

21 MR. WEINBERGER: No, I am not going
22 to redirect him. I'm going to -- I want you to
23 allow him to finish his answer. Go ahead,
24 Dr. Malone.

25 Q. (BY MS. FUMERTON:) Okay. And

1 again --

2 MR. WEINBERGER: Go ahead, Dr.

3 Malone?

4 A. This particular interaction does not
5 involve the benzodiazapine class.

6 Q. (BY MS. FUMERTON:) Okay. And one of
7 the -- you did not identify as one of the eight
8 high priority DDIs an opioid and a muscle relaxer,
9 correct?

10 A. That is correct.

11 THE REPORTER: I didn't understand
12 that last word.

13 Q. (BY MS. FUMERTON:) Muscle --

14 A. Relaxant.

15 Q. An opioid and a muscle relaxer,
16 correct?

17 A. It was not one of the algorithms we
18 developed, no, that combination was not.

19 Q. And if you turn to Page 2 of your
20 article that is Exhibit 6. About the
21 second-to-last paragraph before Objectives, it
22 says, "Unfortunately, most systems currently
23 trigger DDI alerts based on the pair-wise
24 combinations of the drugs involved. Thus, there
25 tends to be little or no consideration by the

1 systems of contextual factors. However, the
2 specificity of an alert to an individual patient
3 characteristics play a major role in alert
4 acceptance."

5 Do you agree with those statements?

6 A. Yeah. So the -- so the notion here
7 is that when an alert appears, it should be
8 relevant to the patient, it should be relevant to
9 the drug and relevant to the situation.

10 So when there's -- you know, to put
11 it in context of the opioids, when a medication is
12 for legitimate medical use, you know, for a patient
13 that needs the medication, you shouldn't be firing
14 alerts that say, you know, do not dispense this
15 medication. Just like in drug interactions, you
16 should not be telling people that, hey, there's a
17 major problem when, in fact, because of the
18 contextual situation, we shouldn't be saying, you
19 know -- you know, warning there's a problem when
20 there's really not. It gets back to this notion of
21 crying wolf.

22 Q. Right. So -- and context matters.
23 So for example, if you have a blanket alert that
24 anything over twenty-five miles get flagged, but
25 you are sitting in Ohio and the Cleveland Clinic is

1 more than twenty-five miles away, that flag doesn't
2 make any sense, correct?

3 MR. WEINBERGER: Objection, form.

4 A. It depends on many other situations
5 as to, you know, how -- you know, how that
6 information was generated. So it may make a lot of
7 sense that that is a flag that is important. So --
8 and it may not. So my -- the premise of this paper
9 is we put all of these into -- more than just a
10 yes/no dichotomous situation. These algorithms
11 that we tested in this particular paper consider a
12 number of different factors before an alert would
13 be generated or we would recommend that an alert be
14 generated. Or in the absence of that information,
15 that an alert be generated. And in situations
16 where the patient is not at risk, then the alert
17 would not be generated.

18 So that is the whole premise of the
19 paper. It is not that we are saying don't generate
20 alerts; it is that we are saying you need to make
21 an alert be smart to the situation in which the
22 patient, the drug and the provider find themselves
23 in.

24 And I want to say the provider,
25 meaning inpatient versus outpatient, you know, and

1 that could extend to an oncology physician versus a
2 family practice physician versus a neurologist
3 versus -- any other sort of other characteristics
4 that could be -- or should be incorporated into
5 these systems.

6 Q. (BY MS. FUMERTON:) And your
7 algorithms oftentimes use lots of different data
8 points pulled together in a complicated fashion to
9 make that determination, because you are trying to
10 put in as much context as possible; is that right?

11 A. Yeah, to the extent the evidence
12 supports it, yes.

13 Q. And so to go back to my statement,
14 you agree that context matters with respect to
15 alerts, right?

16 A. I would say generally, yes, that is
17 true.

18 Q. So again, if you are sitting in the
19 middle of Ohio, the Cleveland Clinic, which is
20 probably one of the most well-respected health
21 systems, is sitting more than twenty-five miles
22 away from your pharmacy, having a blanket alert
23 that every time a medication that comes from the
24 Cleveland Clinic gets flagged because it is
25 twenty-five miles -- more than twenty-five miles

1 away makes no sense, correct?

2 MR. WEINBERGER: Objection, form.

3 A. It would depend, so -- I don't know.

4 Q. (BY MS. FUMERTON:) It would depend
5 on what?

6 A. On the other attributes and what
7 the -- how that alert was configured and for what
8 it was configured for. So there's -- you are
9 giving me one piece of information that would be --
10 you know, that -- you know, I don't know the other
11 pieces of the information that would be relevant.
12 And -- you know, so it just -- you are asking a
13 very -- what sounds like a very simple question,
14 but it is more complex than that.

15 Q. But it is a very simple -- it is a
16 very simple slide, so that is why I want to get to
17 this point of your article and studying this issue
18 of alert fatigue.

19 And so if you have a very simplistic
20 flag like anything over twenty-five miles, and you
21 don't take into context the fact that the Cleveland
22 Clinic is more than twenty-five miles away, having
23 a singular flag of just twenty-five miles makes no
24 sense and contributes to the alert fatigue,
25 correct?

1 MR. WEINBERGER: Objection, form.

2 Asked and answered. Go ahead.

3 A. I guess I will just refer to my
4 previous answer.

5 Q. (BY MS. FUMERTON:) Well,
6 respectfully, you didn't answer -- you didn't give
7 an answer to my previous question. And so I will
8 ask it again.

9 A. Okay.

10 Q. We are talking about, you know, a
11 single flag, not in context, of twenty-five miles,
12 saying that you should review and you should alert
13 on any prescription that comes in for more than
14 twenty-five miles away. That is exactly the type
15 of simplistic flag that you have been researching
16 ways to avoid, correct?

17 MR. WEINBERGER: Objection.

18 A. Actually, we haven't been doing any
19 of the geospatial analysis that you are talking
20 about. And as you indicated earlier, in terms of
21 excessive use of opioids has not been my primary
22 area of research. And I -- so given those two
23 facts, the question you are asking is really beyond
24 my expertise of whether that is an appropriate flag
25 or not or whether that is a simplistic flag that

1 should be used or shouldn't be used. That is not
2 my area of expertise.

3 Q. (BY MS. FUMERTON:) And the
4 excessive -- what is the excessive use of opioids
5 is also not your area of expertise, correct?

6 A. Determining, you know, the decision
7 point what is an excessive use of opioids, that is
8 correct, that is not my area of expertise. My area
9 of expertise is creating algorithms that can
10 identify potential problems and assessing those
11 algorithms and using the data that is available to
12 me to help contextualize or make that information
13 useful to the person having to make a decision
14 based on that information.

15 Q. Okay. So take your expertise,
16 though, which is creating these algorithms.

17 A. Yes.

18 Q. And with your expertise, you would
19 never create such a simplistic algorithm that
20 simply flags something as simply inappropriate
21 because it is more than twenty-five miles away,
22 correct?

23 MR. WEINBERGER: Objection, form.

24 A. That is not my area of research, so I
25 can't -- you know, I can't say that it is -- I

1 would or wouldn't do that. It is just not
2 something -- it could be done is what I am saying.
3 That is the basis of my report. Whether it is
4 appropriate or not or whether it is relevant or not
5 is for others to decide. That is not my area of
6 expertise.

7 Q. (BY MS. FUMERTON:) So you don't
8 think that having an alert that would flag all
9 prescriptions coming in more than twenty-five miles
10 away would result in alert fatigue?

11 MR. WEINBERGER: Objection, form.

12 A. I don't know how many prescriptions
13 come in from more than twenty-five miles away. So
14 may be a very few, may be a lot; it probably
15 depends upon the pharmacy.

16 If you are in Rangely, Colorado,
17 where you have, you know, probably two prescribers
18 within a hundred miles of you, just about every
19 prescription that doesn't come from those two
20 prescribers is more than a hundred miles away and
21 may not be a relevant alert.

22 In the middle of Ohio, you know, it
23 may make sense that that is an appropriate --
24 inappropriate distance. That is not my area of
25 expertise.

1 So contextual doesn't just mean that
2 the patient -- only taking into account the
3 patient. It means that, you know, for one
4 pharmacy, it might be one radius or another
5 pharmacy it would be another radius. And what
6 constitutes an excessive amount of alerts, you
7 know, I don't know.

8 Every prescription, you know, we are
9 not talking about every prescription, I don't
10 think, in this litigation. We are talking about
11 opioids which, you know, isn't every prescription.

12 So, you know, you are
13 overgeneralizing, I think, and so I can't -- you
14 know, so, therefore, I want to make sure that my
15 answer is clear, that it depends upon how this is
16 operationalized as to whether it would be
17 appropriate or inappropriate and result in excess
18 alerts or maybe not enough. I don't know.

19 Q. (BY MS. FUMERTON:) So you are
20 offering no opinions in this case as to what
21 appropriate alerts might be; is that right?

22 A. My area of expertise is in drug
23 interactions, and to the extent that opiates are a
24 part of drug interactions, then I think my opinion
25 is relevant. In terms of determining what sort of

1 alerts should be generated with respect to opioid
2 prescriptions, those have been defined by somebody
3 else. I didn't design those rules. I haven't
4 studied those rules. I haven't studied the
5 implementation of those rules.

6 Q. So you -- so you don't know if those
7 rules -- it would make sense -- you are offering no
8 opinion one way or the other as to whether it makes
9 sense to implement the rules that other people are
10 opining on, correct?

11 A. That is right. I am not. I am not
12 saying that they are good or bad rules.

13 Q. You are just saying that you can
14 develop systems that have alerts; is that right?

15 A. Uh-huh.

16 Q. But you are offering no opinion as to
17 what those alerts might be?

18 A. That's correct.

19 Q. And you are offering no opinion as to
20 whether or not any of the pharmacy defendants, in
21 fact, had systems that alerted, correct?

22 A. Restate that question. I want to
23 hear it again. I'm sorry.

24 Q. You are not opining on -- your
25 opinion -- and I don't mean to -- let me ask it

1 this way: You are opining that it is possible to
2 create systems that have alerts. You have no
3 opinion on what that system should look like,
4 correct?

5 A. I would -- no, I am not going to
6 agree with that statement. I have a sense of what
7 that system should look like. I just don't know --
8 so in the context of red flags -- so I will use
9 that term because it is used in many of the
10 documents by the DEA and others. The DEA developed
11 the red flags. I don't know -- I am not an expert
12 on the development of red flags with respect to
13 opioid medications, and I don't know if the DEA's
14 decision rules with respect to those are
15 appropriate or inappropriate. I haven't studied
16 that, so I am not trying to come up with a set of
17 rules or say that I have a set of rules that should
18 have been used.

19 I am saying that within these
20 organizations, they had the wherewithal and the
21 means and the capability. And, in fact, the
22 evidence presented to me as part of my review
23 offered solutions to operationalize those rules or
24 those red flags.

25 My expertise is that those systems

1 were in place and could have generated those
2 warnings had these defendants chose to do that.
3 And, in fact, I think, based upon, you know, given
4 the timeline, I think some of those systems have
5 actually been implemented. So -- but I think the
6 -- the basis of my testimony is on the fact that,
7 you know, even though these things have been in
8 place, the data systems have been in place, the
9 computers have been in place for many, many years,
10 it is only recently that those tools have been made
11 available to the pharmacists.

12 So whether those tools are using the
13 right cut point, twenty-five miles, thirty miles,
14 ten miles, I have no opinion as to whether that is
15 an appropriate rule and whether that would generate
16 too many alerts.

17 Q. But your research is in -- and we
18 have looked at a lot of it today -- in alert
19 fatigue, correct?

20 A. As it applies to drug interactions,
21 yes.

22 Q. Well --

23 A. So --

24 Q. Is there a reason why alert fatigue
25 would apply differently for drug interactions as

1 opposed to any other alert?

2 A. Yeah, most definitely, yeah, most
3 definitely. There are alerts that you don't -- in
4 situations where it makes -- the patient could be
5 harmed, have a tremendous degree of harm by the
6 administration of two agents or even a single agent
7 under particular circumstances. And that is what
8 these systems are designed to prevent. They are
9 designed to engage the end user, the physician to
10 pharmacist, to assist them in the knowledge that
11 they need to have or -- I shouldn't say the
12 knowledge, the information -- they have the
13 knowledge. It is providing them useful information
14 at the time that they are making the decision.

15 So from my perspective, you know, if
16 you don't provide -- given the types of -- I
17 shouldn't say the types -- the number of different
18 medication orders that come through a pharmacy in a
19 given day, a small proportion of those -- or a
20 proportion of those are going to be related to
21 opioids. And therefore, you know, when those
22 orders come through, you know, there is a
23 potential, you know, for any one of those orders to
24 fall into one of those categories the DEA has
25 classified as a red flag.

1 And there are systems in place to
2 help the pharmacists adjudicate that particular
3 medication order against those -- should be, the
4 system should be in place. The data is there, the
5 system wasn't -- to adjudicate that red flag or
6 those red flags.

7 Q. If you are not -- if you are not
8 opining on whether or not a system should have any
9 particular red flag or not, how do you know whether
10 the data is there? Do you even know what the data
11 is to assert -- to be able to figure out whether or
12 not the red flag can alert?

13 A. You know, the great thing about
14 pharmacy --

15 MR. WEINBERGER: Objection to form.
16 Go ahead. Go ahead.

17 A. The great thing about pharmacy and
18 pharmaceuticals is that the data fields have
19 largely been standardized across the entire
20 industry for many, many years.

21 As I indicated in my report, the
22 National Council for Prescription Drug Programs has
23 standardized the submission of claims data and,
24 therefore, largely the submission of how this data
25 is stored within these computer systems that allows

1 us to be able to say, yeah, these medications are
2 opioid medications.

3 It is easy for us to identify those
4 based upon attributes that are maintained in these
5 databases, by not only the pharmacy but also the
6 drug knowledge vendors, et cetera.

7 So they have prospective DUR systems
8 capable of using that information to provide the
9 pharmacist with assistance in dispensing the
10 medication.

11 So I am suggesting that the systems
12 are -- have largely been intact for nearly twenty
13 years to allow the organizations -- and I will use
14 that term loosely here -- organizations to develop
15 tools to help the pharmacists adjudicate
16 prescription orders, including opioid medications.
17 And they do that and have done that since 19 --
18 over 1999 -- 1990, excuse me, it was passed where
19 the pharmacist, via that particular piece of
20 federal legislation, was required under prospective
21 drug utilization review to do a number of
22 activities. Computer systems have made those
23 activities much easier to be done as a part of
24 their day-to-day practice. Alerts --

25 Q. (BY MS. FUMERTON:) Okay. I think --

1 I am going to interrupt you.

2 A. Sorry.

3 Q. You are so far afield of my question
4 at this point in time.

5 MR. WEINBERGER: If you -- wait.
6 Wait. Wait.

7 Q. (BY MS. FUMERTON:) Your opinion is
8 that --

9 MS. FUMERTON: No. No.

10 Q. (BY MS. FUMERTON:) So your opinion
11 is that -- that the pharmacies should have provided
12 tools to help the pharmacists adjudicate
13 prescription orders. Is that right?

14 A. They do and they should. They do do
15 it via prospective DUR.

16 Q. What do you think they should do
17 differently than they already are doing?

18 MR. WEINBERGER: Tara, please. Tara,
19 please.

20 MS. FUMERTON: Pete, stop. I don't
21 care -- I want to ask my question.

22 MR. WEINBERGER: I'm going to
23 terminate the deposition because I am not going to
24 let you continually cut off this witness.

25 Now, if you go back --

1 MS. FUMERTON: He went on a -- he
2 went on a soliloquy so far afield, that for the
3 last two minutes that -- no, we have to be able to
4 have a deposition that is answers -- questions and
5 answers, not just self-serving statements.

6 MR. WEINBERGER: Wait. Now you are
7 interrupting me. Now you are interrupting. Please
8 let me have my say on the record, and then you can
9 say whatever you want to say.

10 Now, if you go back to the question,
11 the convoluted question that you asked before he
12 gave you that long answer, I think you will see the
13 reason why the answer was the way it was.

14 Now, you keep asking the same
15 question over and over again, and you don't like
16 the answers that you are getting. I am sorry about
17 that.

18 But I am not going to permit you to
19 continue to take this deposition while you are
20 interrupting the witness. We didn't -- we don't do
21 that with your witnesses; we don't do that with
22 your experts, and you are not going to do it with
23 this expert.

24 MS. FUMERTON: Are you done lecturing
25 me? Because I don't want to hear it, Pete. So

1 let's continue on. I will ask my question --

2 MR. WEINBERGER: I am warning you. I
3 am warning you. If you continue to do it, I am
4 going to stop the deposition.

5 MS. FUMERTON: You do what you feel
6 you need to do, Pete. But, again, I can ask
7 questions and get answers to them.

8 So -- and I have had Special Master
9 Cohen direct witnesses to answer yes/no questions,
10 "yes, no" and you have been there when he has done
11 that as well.

12 Q. (BY MS. FUMERTON:) So again, I am
13 going to go back to what I was asking before. What
14 specifically do you think the pharmacies should
15 have been doing that they were not doing?

16 MR. WEINBERGER: Objection, form.

17 A. The pharmacy -- the pharmacist was
18 operating in a data vacuum with respect to red flag
19 warnings, as far as I could tell from the materials
20 provided to me, you know, by the various
21 defendants.

22 I saw no evidence that they had used
23 the data at their disposal to create a dashboard, a
24 speedometer, so to speak, that would allow them to
25 inform -- help inform their decision process about

1 dispens -- as to whether a particular opioid
2 prescription was legitimate or not.

3 Q. (BY MS. FUMERTON:) Can you point to
4 any particular pharmacy that has done what you
5 think should have been done in the entire industry?

6 A. Well, IMS Health provided -- whether
7 they have done, implemented it or not is another
8 matter. I cannot point to a particular pharmacy.

9 But IMS Health provided such a
10 dashboard, offered such a dashboard to one of the
11 defendants in 2012, I believe. And it had those
12 elements that I am referring to, you know, those
13 red flags and an approach to presenting that
14 information.

15 So is it -- to me the question is was
16 it technically feasible to create such a dashboard?
17 Yes, it was. It is up to the defendants to ask
18 the -- answer the question of why they did or
19 didn't do it. So --

20 Q. And you have no opinion as to whether
21 or not they did or did not do that, correct; you
22 don't know one way or the other?

23 A. Based upon what I have seen, I have
24 seen no evidence that they did that. So if the
25 materials that I reviewed -- so the materials I

1 reviewed didn't provide evidence that they had done
2 that in the time frame that I was instructed to
3 consider my comments or my expert opinion, which
4 was --

5 Q. What is the time frame that you were
6 asked to consider?

7 A. I believe it was up through 2018.

8 Q. Okay. So, for example, we are going
9 to get there in a second, but I am sure you noticed
10 there weren't that many that you looked at. The
11 last Walmart document you looked at was from 2012.
12 Did you ask to look at any Walmart documents after
13 2012?

14 A. I didn't note the date of the
15 materials that were presented to me.

16 Q. You don't know --

17 A. So if the date was --

18 Q. Well --

19 A. If the date was on the document, I
20 noted that. But I don't know what other documents
21 Walmart has generated since 2012 that would be
22 relevant to this case. That is information I don't
23 have at my disposal. I only know that what was
24 provided to me.

25 Q. Who provided --

1 A. So if they had -- well, I am assuming
2 that was part of the discovery process, so --

3 Q. Okay. So let's stop here for a
4 second. Why don't you pull out your report, and we
5 are going to come back to this other stuff, but I
6 want you to turn to Page 3 of your report.

7 A. Okay.

8 Q. These are listed -- Page 3 of your
9 report, you list the materials reviewed that you
10 relied on as a basis for your report, correct?

11 A. Yes.

12 Q. And it goes on to Page 4 for other
13 defendants as well, right?

14 A. That is correct, yes.

15 Q. For Walmart, you relied on four
16 documents; is that right?

17 A. Yes.

18 Q. Is it your understanding that those
19 were the only four documents that Walmart has
20 produced in this litigation?

21 A. No, I'm sorry. You said Walmart?
22 I'm sorry.

23 MR. WEINBERGER: Tara, it is --
24 Number 1 is testimony and exhibits, right? You are
25 talking about there's --

1 MS. FUMERTON: Hey, Pete, I'm asking
2 him the question. You can't answer the question
3 for him. I am asking him. Please don't answer the
4 question for the witness.

5 A. So under Number 1 for Walmart,
6 testimony and exhibits under deposition, under the
7 deposition for Mr. Townzen, there were probably
8 twenty or thirty different PDFs of the ConnexUs
9 software system that were displayed there. So
10 those were usually manual -- manuals about how
11 those systems work.

12 Q. (BY MS. FUMERTON:) You think there
13 were twenty or thirty manuals, that is your
14 testimony, produced by Walmart?

15 A. No. No. No. Well, there's probably
16 not twenty -- probably not twenty documents but
17 there were a large number of documents, PDF files,
18 of different sections of the manual for ConnexUs.

19 Q. So is it your understanding that this
20 document that you listed here, the testimony and
21 exhibits from Darren Townzen's deposition and the
22 three other ConnexUs documents, are the only
23 documents that were produced in litigation?

24 MR. WEINBERGER: Objection, form.

25 A. I have no knowledge.

1 Q. (BY MS. FUMERTON:) If there had been
2 documents that were relevant after 2012, would you
3 have wanted to see those?

4 MR. WEINBERGER: Objection, form.

5 A. Sure.

6 Q. (BY MS. FUMERTON:) Did you ask
7 plaintiffs to see them?

8 MR. WEINBERGER: Objection, form.

9 A. I did not.

10 Q. (BY MS. FUMERTON:) Did you tell
11 plaintiffs what type of documents you would like to
12 see?

13 MR. WEINBERGER: Objection, form.

14 A. The main piece of evidence I was
15 looking for was information about the operations of
16 the organization, so to the extent that that was
17 provided to me, that is what I relied on.

18 Q. (BY MS. FUMERTON:) Are you aware
19 that there were hundreds of policy and manuals that
20 were produced by Walmart in this litigation, none
21 of which you cite here?

22 MR. WEINBERGER: Objection, form.

23 A. I have no knowledge.

24 Q. (BY MS. FUMERTON:) So plaintiff
25 selected which documents you should review and base

1 your opinions, is that correct?

2 MR. WEINBERGER: Objection, form.

3 A. I don't know.

4 Q. (BY MS. FUMERTON:) How did you
5 select the documents that you were to review, then?

6 A. I don't know who came up with this
7 list.

8 Q. You did not come up with this list;
9 is that right?

10 A. No. I did not come up with this
11 list. This is what I was provided.

12 MR. WEINBERGER: We will stipulate
13 that we came up with a list of documents and
14 provided them to him.

15 Q. (BY MS. FUMERTON:) So you did not
16 have any understanding of who was selecting the
17 documents that were being provided to you?

18 A. What do you mean by "understanding"?

19 Q. Did you understand who was selecting
20 the documents for you to review and base your
21 opinions on?

22 MR. WEINBERGER: Objection, form.

23 A. Again, I am trying to understand your
24 question. My apologies. Could you please rephrase
25 that question?

1 Q. (BY MS. FUMERTON:) What was your
2 understanding of who selected the documents for you
3 to review?

4 A. I -- hmm. I am trying to recall the
5 conversation about --

6 MR. WEINBERGER: Anything that you
7 and I discussed, I don't want you to disclose.
8 They are privileged.

9 Tara, I have already told you that we
10 are stipulating that I selected, you know, as part
11 of the plaintiff's team, the documents to be
12 provided to Dr. Malone for his review.

13 MS. FUMERTON: I am entitled to
14 understand what the expert's understanding was of
15 the documents on which he is basing his opinion.

16 Q. (BY MS. FUMERTON:) So, Dr. Malone,
17 are you telling me that you had no understanding of
18 what documents or what universe of documents you
19 were looking at?

20 MR. WEINBERGER: Objection. Form.

21 A. I was -- so I was not given a list of
22 potential documents to examine and then selected
23 only certain documents. So the focus of my expert
24 witness testimony has to deal with the feasibility
25 to generate warnings to the pharmacists. So my --

1 my expectation was that I was provided materials
2 that would allow me to assess the feasibility of
3 generating those warnings.

4 Q. (BY MS. FUMERTON:) Generating what
5 warnings?

6 A. The feasibility. So we have been
7 talking about red flags alerts, although I know you
8 haven't used the term. That is, I guess, the
9 general premise here is that the DEA has come out
10 with warnings that pharmacists should -- pharmacies
11 and pharmacists and prescribers should all be
12 cognizant of when dispensing -- prescribing and
13 dispensing opioids and other medications that could
14 contribute to abuse of these controlled substances,
15 these dangerous substances.

16 So my scope of work was determining
17 whether the systems were in place to be able to
18 generate algorithms that would help the pharmacist
19 fulfill that duty and help the pharmacy fulfill
20 that duty, because it is not just the pharmacist.
21 Many times pharmacists don't even see the warnings.
22 They are presented to a technician.

23 Q. What is your basis for asserting that
24 the DEA has come out with warnings that pharmacies
25 and pharmacists and prescribers should be cognizant

1 of when dispensing and prescribing opioids?

2 A. The Controlled Substances Act --
3 well, I may not -- there is a document that I have
4 seen that part of my former profession, pharmacy,
5 that had a series of warnings that should not be --
6 that should be considered when dispensing opioid
7 medication. And, in fact, I think it is within
8 these documents as well.

9 Q. Which document are you relying on for
10 that?

11 A. I would have to investigate. So if
12 you go under CVS, Item Number 5, 2012, the CVS
13 Corporate PowerPoint outlining red flag reports and
14 also the next document, PowerPoint outlining red
15 flags and their enhanced program.

16 Q. And so your understanding is that
17 those documents represented what the DEA said were
18 appropriate red flags, and you designed the system
19 to flag --

20 A. Those are consistent with what the
21 DEA -- I'm sorry. I talked on top of you. Please
22 restate.

23 Q. You said they are consistent with
24 what the DEA said. How do you know that? How do
25 you know that those are consistent with what the

1 DEA said? To answer that question, wouldn't you
2 have to know what the DEA said?

3 A. Yes, you would. And those are
4 consistent with other documents, other professional
5 trade publications that I have seen associated with
6 red flag warnings.

7 I am looking to see if there's
8 another document that had it.

9 Q. You testified earlier that all the
10 documents that you relied upon --

11 MR. WEINBERGER: I think he was
12 still -- I think he was not finished with his
13 answer, Tara. He was looking for additional
14 information. Let him finish his answer.

15 THE REPORTER: Somebody is not muted.
16 I hear something in the background.

17 MR. WEINBERGER: There's some noise
18 outside my window. Let me just see if that -- is
19 that better?

20 THE REPORTER: Yes. It is not
21 interfering with me hearing it. We are okay.

22 A. I probably need to go to the
23 deposition materials for the various defendants. I
24 believe there was information within those
25 documents, but I don't recall which of them had

1 that information.

2 Q. (BY MS. FUMERTON:) Do you know how
3 many documents the pharmacy defendants produced in
4 this case?

5 A. I do not.

6 Q. Would you be surprised to learn that
7 there were hundreds of thousands, if not millions
8 of pages of documents produced by the pharmacy
9 defendants?

10 A. No, I would not be surprised. These
11 are very large organizations.

12 Q. How many pages do you think you
13 looked at?

14 A. Oh, more than five hundred. I
15 probably looked at closer to a thousand pages of
16 documents across the various depositions and
17 groups.

18 Q. And it took you seventeen hours to do
19 that, right?

20 A. Uh-huh.

21 Q. Did you understand that you were
22 provided with all relevant documents you would need
23 to form your opinions in this case?

24 A. I was -- whether it was all, no.

25 Q. Do you feel comfortable giving an

1 expert opinion if you don't have all relevant
2 documents?

3 MR. WEINBERGER: Objection, form.

4 A. If the Court would like me to review
5 all of the relevant documents, I would be happy to,
6 if they feel that there's other documents that are
7 relevant.

8 Q. (BY MS. FUMERTON:) That wasn't my
9 question. My question was: Do you feel
10 comfortable giving an expert opinion if you don't
11 have all the relevant information?

12 MR. WEINBERGER: Objection, form.
13 Assumes facts not in evidence.

14 A. I don't know if I don't have all of
15 the relevant information.

16 Q. (BY MS. FUMERTON:) Do you know that
17 you have all the relevant information?

18 A. I know what I have. I don't know
19 what I don't know.

20 Q. Did you ask plaintiffs what they
21 didn't give you?

22 A. I'm sorry. I didn't hear the
23 question.

24 Q. Did you ask plaintiffs what documents
25 they had they did not give you?

1 MR. WEINBERGER: Objection, form.

2 A. No, I did not.

3 Q. (BY MS. FUMERTON:) So you just
4 assumed, as a basis for your expert opinion, that
5 plaintiffs gave you the relevant documents
6 necessary to form your expert opinion, correct?

7 A. That is correct. I assumed that I
8 had the relevant documents that were necessary for
9 me to evaluate this situation, and my opinion is,
10 whether or not the data was in place within these
11 organizations, the data systems were in place
12 within these organizations.

13 And I would -- I would have known
14 that regardless of whether the -- you know, I had
15 those other hundred thousand documents or something
16 that you are referring to because the practice of
17 pharmacy has been standardized with respect to
18 these data elements that we have been referring to.

19 There's no dispute scientifically
20 about what information is available as -- drug
21 information is available as a part of the
22 dispensing process, in a general sense, that could
23 have been used to inform a practitioner about
24 whether a medication was being used for a
25 legitimate medical purpose. That is not in

1 dispute. That is -- we have been working with this
2 data since the 1990s. So I don't need a document
3 to generate -- to state that that is the case.
4 What --

5 Q. So to be clear -- go ahead.

6 MR. WEINBERGER: Objection. I don't
7 think he finished his answer.

8 MS. FUMERTON: I stopped, Pete.

9 Q. (BY MS. FUMERTON:) Go ahead,
10 Dr. Malone.

11 A. So the premise of my expert testimony
12 is whether the data systems were available to be
13 able to create these warning systems.

14 Q. And you knew those data systems were
15 available without even looking at a single
16 document, correct?

17 A. Because it is the practice of
18 pharmacy -- these data -- my own research has
19 demonstrated the ability to pull the data out of
20 these organizations. I used -- I have used data
21 from CVS. I have used data from Walgreens. So I
22 know that those data exist within those systems.
23 Because it is part of the business of pharmacy.
24 And it is a part of the pharmacy practice
25 environment that these data exist.

1 They are required by state law for
2 some data elements. They are required by federal
3 law for other data elements. They are required by
4 prescription standards for other data elements.

5 So there's no dispute, in my opinion,
6 about whether the data systems existed within the
7 organizations.

8 Q. Right. And you knew that without
9 even looking at a single document or even
10 talking -- right?

11 A. Yes.

12 Q. Okay. And you are not opining that
13 any defendant failed to comply with any of those
14 state or federal requirements as to what data they
15 should have maintained, correct?

16 A. That's correct. I have no opinion on
17 that matter.

18 Q. And really, the data that you are
19 talking about is the dispensing data, right?

20 A. Primarily, you are right. So when
21 you say "dispensing data," it includes, obviously,
22 you know, the prescription information. So
23 information about the prescription, information
24 about the prescriber, information about the
25 patient, information about the drug product.

1 But there's other data that these
2 organizations have at their disposal as well that,
3 you know, are relevant, especially as it relates to
4 purchasing. So those data are maintained by these
5 systems -- you know, within these systems. So --
6 and how you get those medications from the
7 wholesaler to the pharmacy, those systems have been
8 established for a long period of time.

9 Granted, it has been a long time
10 since I have been a pharmacist, but even back, you
11 know, thirty years ago we used electronic data
12 systems to transfer that information to the drug
13 wholesalers to get the authority to be able to fill
14 the prescriptions. Those systems have been in
15 place a long, long time.

16 Q. So the materials you reviewed
17 actually weren't relevant to your opinions because
18 you held those opinions before you even looked at
19 the documents, right?

20 A. All drug interaction alerts are based
21 upon the availability of those data as well. So,
22 yes. Now, what these documents provided to me was,
23 I guess, more detail about how -- what their
24 systems had within their system -- within their
25 organization and how they operationalized some of

1 that data.

2 Q. Great. So let's talk about that.
3 Give an example of how Walmart operationalized its
4 dispensing data for drug-drug interaction.

5 A. Walmart, I don't think, provided
6 those level of details. CVS did, and more so, I
7 believe. And those were in the depositions, right.

8 So I asked within those depositions
9 of the representatives of Walmart, CVS, Rite Aid,
10 what have you, there were statements made by those
11 individuals representing that they had used either
12 First Databank or Medi-Span as a part of their drug
13 distribution systems. So which particular one they
14 used, you know, was probably dependent upon
15 corporate decisions.

16 Q. What is your basis for saying that
17 Walmart did not provide that level of detail?

18 A. I am sorry. Walmart -- I did not
19 receive that level of detail about -- so you asked
20 me the question, you know, how did Walmart
21 determine its drug-drug interaction systems or how
22 did they operationalize their drug interaction
23 systems.

24 Well, I think it is not germane to
25 this case as to which drug knowledge database

1 vendor they used, how they laid out those tables
2 within their ConnexUs RX -- ConnexUs system. But
3 their screen shots that were provided to me
4 indicated that they were using drug utilization
5 review processes within their organization.

6 Q. So what was Walmart doing -- not
7 doing that you think it should have been doing?

8 A. As it relates to opioids, in my
9 opinion -- and, you know, maybe it is doing
10 something and I am not aware of it.

11 But it should be providing the
12 pharmacists with information in realtime about
13 those attributes that would suggest that the
14 medication is being used inappropriately. And when
15 I am saying medication, I am talking about opiates,
16 opioids.

17 Q. But you don't know and you are
18 offering no opinion --

19 MR. WEINBERGER: Wait --

20 Q. (BY MS. FUMERTON:) -- what those
21 attributes were, right? You are not offering any
22 opinion on what those attributes should be?

23 A. No, because those have been defined
24 by others. I'm not -- I'm not saying that those
25 are the right attributes or the wrong attributes.

1 We have already covered that.

2 Q. (BY MS. FUMERTON:) Right. So you
3 are not offering any opinion as to whether or not
4 Walmart was correctly evaluating the relevant
5 attributes, correct?

6 A. That is not what I said. You said --
7 please restate the question to make sure I
8 understood.

9 Q. You said I am not saying -- this is
10 quote, "I am not saying that those are the right
11 attributes or the wrong attributes; you have
12 already covered that." I agree we have already
13 covered that.

14 So you are not offering opinions one
15 way or the other as to whether Walmart was
16 appropriately identifying attributes?

17 A. That is correct.

18 Q. And that is true for all the other
19 pharmacy defendants in this case too?

20 A. That is correct.

21 Q. You mentioned the NCPDP standard,
22 correct?

23 A. Yes, I did.

24 Q. And specifically, you referenced
25 Script 5.0, right?

1 A. I did, yes.

2 Q. And you suggested that that data
3 standard is related to the submission of third
4 party claims to PBMs, right?

5 A. Yes, I did. Well, Script 5.0 --

6 Q. But Script 5.0 is the electronic --
7 MR. WEINBERGER: You are talking
8 over --

9 THE REPORTER: I didn't hear you.

10 MR. WEINBERGER: You are talking over
11 him. He was trying to answer your question, finish
12 his answer.

13 A. NCPDP does a fairly lousy job of
14 delineating what is their electronic prescribing
15 initiative and what is their dispensing initiative,
16 in my opinion.

17 The version of the document that I
18 have, which 5.0 is dated, it is no longer in
19 practice, but as I indicated in my statement, that
20 they have updated that.

21 I don't subscribe to NCPDP, so I am
22 not familiar with the data elements in the latest
23 version of their third-party claims processing
24 standard.

25 But, yeah, they do -- to answer your

1 question, they do have an electronic prescribing
2 standard as well as a third-party claims standard.

3 Q. (BY MS. FUMERTON:) You just don't
4 know which is which, right?

5 A. Well, as I have indicated, NCPDP does
6 a poor job of naming their standards. I know which
7 is which, but how they refer to them has varied
8 over time.

9 Q. Okay. So -- okay. So what does
10 NCPDP call the standard relating to the submission
11 of the claims to PBM?

12 A. They had a very -- I am trying to
13 recall off the top of my head. The -- because they
14 have changed that name over time.

15 Like I said, they had a very generic
16 name for a while. So off the top of my head, I'm
17 not sure what they are doing. I would have to go
18 back and look.

19 Q. Is your report accurate?

20 A. As I stated in the report, the
21 document I have from 2005 called it Script Version
22 5 --

23 Q. Okay.

24 A. I know there was Version 5.1, Version
25 5.2, Version 5.3, etcetera. So what version they

1 are currently on, I am not sure. The reason I
2 mentioned this particular standard is it is, and
3 has been, the pharmacy claims data standard, or
4 variants thereof, since this period of time and
5 probably even before that.

6 Q. Just so the testimony is clear, it is
7 your position in your expert testimony that Script
8 Version 5.0 at some point in time was the NCPDP
9 standard relating to the submission of third-party
10 claims to PBM; is that correct?

11 A. It is -- I want the ability to
12 clarify that later.

13 Q. Well, okay. This is your expert
14 report.

15 A. So -- I recognize that. I may have a
16 technical error there.

17 Q. You are unsure of whether that
18 information that you reviewed and how you describe
19 it is accurate; is that true?

20 A. Not how I describe it. It is what it
21 is called. So whether it is considered Script or
22 another name was applied to it -- early on, they --
23 as I mentioned early on -- this is before
24 electronic prescribing. Electronic prescribing has
25 only been around for like since the last -- the

1 last fifteen years or so. So this document refers
2 to a standard that was in use well before then.

3 Q. You just don't know what the standard
4 was called?

5 A. Yeah. I may have misrepresented the
6 name of the standard. But the data elements are --
7 the version that I referred to is accurate, and the
8 data elements that are in that version are
9 accurate.

10 Q. What do you mean the version that you
11 referred to is accurate?

12 A. Well, the document that I had had
13 Version 5.0. So NCPDP used a -- used a -- used a
14 different naming convention than it uses now, as
15 far as I can recall, so --

16 Q. You agree that when you come up with
17 a hypothetical algorithm in an academic setting
18 that you have to apply it to the real world setting
19 to see if it actually works, correct?

20 A. That is part of the validation
21 process, yes.

22 Q. So the system you claim that the
23 pharmacies should have had, how have you tested to
24 see if those work in the real world?

25 A. So clarify -- please make your

1 question more specific. What systems I am
2 claiming?

3 Q. Well, I have been trying to get that
4 answer too.

5 Whatever the systems are that you are
6 claiming the pharmacies should have implemented,
7 how have you tested to see whether or not those
8 work in the real world?

9 A. I have not been provided the data nor
10 the algorithms to test those systems, although I
11 will refer to the New England Journal of Medicine
12 article, from CVS employees that instituted some of
13 those systems and demonstrated that they could
14 identify prescribers that were prescribing excess
15 numbers of medications.

16 So -- and I --

17 Q. So CVS --

18 A. Go ahead.

19 Q. So CVS was doing what you think it
20 should have been doing?

21 A. Had the capability to do what it
22 should have been doing. They reported it -- they
23 could have been doing that.

24 Q. Do you know whether they were?

25 A. No.

1 Q. Does the article that you reference,
2 Exhibit 3, does that contain all the systems that
3 you think the pharmacy defendants should have been
4 using?

5 A. I am sorry. You are referring to
6 Article 3?

7 Q. Exhibit 3, which is the article that
8 you were referencing, right?

9 A. Okay. You need to refresh my memory.
10 We have talked about several articles. Which --

11 Q. Exhibit 3, the CVS one that you were
12 just referencing.

13 A. I'm sorry. Okay. Restate the
14 question.

15 Q. Does Exhibit 3 describe all of the
16 systems that you think the pharmacy defendants
17 should have been using?

18 A. No.

19 Q. Okay. So you have not tested in any
20 way whether or not the systems you think the
21 pharmacies should have been using could, in fact,
22 have been used in the real world, correct?

23 A. As I stated earlier, I wasn't given
24 the data to test the systems. However, if you look
25 at the SAS program developed by CVS, and that

1 program I referred to previously, the 2012 SAS
2 program written by a CVS vendor, AGI, computing red
3 flags from their dispensing data, and a 2014 SAS
4 program written by a CVS vendor, computing red
5 flags from their dispensing data, both of those
6 documents had information related to the
7 following -- as near as I can remember, the
8 following red flags. [REDACTED]

21 within the store. A whole host of metrics that
22 were generated via those programs.

23 Whether that information -- whether
24 that information was actually presented to a
25 pharmacist as part of their dispensing is -- is

1 unclear to me. I would not provide any information
2 that that information was or was not provided to
3 pharmacists when they were dispensing medications.

4 Q. Is it your expert opinion that all
5 that information that you just described should
6 have been provided to pharmacists when evaluating a
7 prescription?

8 A. In general, yes, if it is relevant,
9 right. So it gets back to the general question --

10 Q. Do you --

11 MR. WEINBERGER: Objection. Let him
12 answer the question, please. Don't interrupt him.

13 A. It gets back to the general question
14 of, you know, is this for a legitimate medical
15 purpose. And to assist the pharmacists in their
16 duties and the pharmacy staff in their duties, you
17 know, prospective drug utilization programs exist
18 within the pharmacy. And, therefore, by extension
19 of that analogy, you know, we provide warnings
20 associated with different types of medications,
21 okay.

22 It is entirely feasible within these
23 organizations to produce those dashboards to give
24 the pharmacists information about how much out of
25 balance, quote/unquote, this prescription they are

1 receiving is relative to other medications being
2 dispensed for that same medication at the same
3 pharmacy or by that same prescriber or given that
4 same distance -- all of those components, the data
5 systems were available and could have been used to
6 provide the pharmacists that information.

7 Q. (BY MS. FUMERTON:) You are saying it
8 could have been. Are you saying it should have
9 been?

10 I am trying to figure out what your
11 expert opinion is. Are you saying that it should
12 have been, all that information should have been
13 provided to a pharmacist on a dashboard for them to
14 look at every time they are filling an opioid
15 prescription?

16 A. That -- they should -- I'm sorry. It
17 is outside my expertise to say it should have been.

18 Q. Can you turn to -- I don't know if
19 you pulled it out. It was Tab 11 in your box.

20 A. No, one second. All right.

21 (Exhibit 7 was marked for
22 identification.)

23 A. Okay.

24 Q. (BY MS. FUMERTON:) For the record,
25 we have marked as Defendants' Exhibit 7 an article

1 titled "Evaluation of Machine-Learning Algorithms
2 for Predicting Opioid Overdose Risk Among Medicare
3 Beneficiaries With Opioid Prescriptions," and it is
4 dated March 22nd, 2019. Is that correct,
5 Dr. Malone?

6 A. Yes, that is correct.

7 Q. And under the abstract, you write or
8 describe, rather, the importance of your study,
9 which states that "Current approaches to
10 identifying individuals at high risk for opioid
11 overdose target many patients who are not truly at
12 high risk." Correct?

13 A. That is written there, yes.

14 Q. Well, was that the importance of the
15 study?

16 A. I am sorry. That question didn't --
17 I didn't hear that question.

18 Q. I am not just asking what words are
19 written in the paper. I am asking if you agree
20 that that is the importance of the study, what is
21 written there?

22 A. I want you to restate the entire
23 question, please.

24 Q. Okay. Do you agree that the
25 importance of the study is that current approaches

1 to identifying individuals at high risk for opioid
2 overdose target many patients who are not truly at
3 high risk?

4 A. I guess the defining question or the
5 defining component of that question is "many."
6 Some patients, yes. They should not be defined as
7 high risk. Others do need to be defined as high
8 risk.

9 Q. Why did you write "many"?

10 A. I guess in a general context. And in
11 this particular paper, we -- we looked at lots of
12 different attributes that might predict
13 inappropriate use. And there's lots of -- as
14 indicated by, I guess, just prescriptions for
15 opioids, there's many medications that are used
16 appropriately for opioids, and then there's a lot
17 of, you know, in my opinion, evidence to suggest
18 that they are overused.

19 So --

20 Q. Sure. Do you agree -- strike that.

21 You agree that many patients can take
22 opioids safely, correct?

23 A. Yes.

24 Q. Do you agree that the vast majority
25 of patients who take opioids take them safely?

1 A. No.

2 Q. What percentage of patients who take
3 opioids do you think don't do so safely?

4 A. I don't know what percentage. I just
5 know -- you used the term "vast majority." That is
6 a nebulous term, and I can't agree with that
7 statement.

8 Q. So you don't know one way or the
9 other. You are not supposed to agree with the
10 statement.

11 You are just saying, I don't know one
12 way or the other whether or not the vast majority
13 of patients who take opioids take them safely
14 because it a nebulous statement?

15 MR. WEINBERGER: Objection, form.

16 A. I don't think anybody is -- well,
17 strike that.

18 I am sorry. I don't want to -- we
19 don't state in this paper whether patients are
20 taking them appropriately. We are focusing on
21 patients that were at risk of an overdose or abuse,
22 I guess, or have a medication overdose -- opioid
23 overdose.

24 So the answer to your question is
25 there's some evidence to suggest that, you know,

1 medications are being used inappropriately and
2 result in opioid abuse or overdose.

3 Q. (BY MS. FUMERTON:) So, right. And
4 so if you look at the results of your study, in
5 fact, on the same page, less than one percent of
6 the subjects of the study taking opioids had an
7 overdose episode, correct?

8 A. I -- I am looking at the data. I'm
9 sorry. I want to answer your question.

10 Q. I can tell you -- yeah. I can point
11 you, and you can tell me if I am looking at the
12 wrong thing.

13 A. Okay.

14 Q. I am looking at the Results section
15 on the first page. And it says .6 percent had at
16 least one overdose episode.

17 A. Yeah, I guess the question becomes --
18 I'm not sure I can conclude what you are
19 suggesting, given that this is a subset of the data
20 that we are talking about here.

21 So I am trying to be precise in my
22 answer to your question. The number that is stated
23 in that Results section is 0.6 percent had at least
24 one overdose. But there were other components
25 within that population that were evaluated.

1 So whether that represents the entire
2 sample, I don't know. And although I am a coauthor
3 on the paper, I didn't do the analysis. My input
4 into this particular paper was more on
5 conceptualization and definitions stage, but I did
6 not run the programs to generate those results.

7 Q. So what if you look to Page -- maybe
8 this will help, on Page 5 of the study, you look at
9 the results and the patient characteristics.

10 A. Yeah. So there -- yes, there we have
11 a little bit more information. So across that
12 group in this data set, the definition of overdose,
13 according to a diagnostic criteria, is shown there,
14 yes.

15 So ranging from relatively low to, I
16 guess, in the high risk group, yes, less than one
17 percent. So your statement is accurate.

18 Q. The objective of your study was to
19 develop and validate a machine-learning algorithm
20 to predict opioid overdose risks among Medicare
21 beneficiaries of at least one opioid prescription,
22 correct?

23 A. Of this particular paper, yes, it
24 was.

25 Q. And the study excluded cancer

1 patients from that algorithm, correct?

2 A. Yes, we did.

3 Q. Why?

4 A. From the standpoint that cancer
5 patients have a unique type of pain and, therefore,
6 may require different dosing of opioid medications.
7 So -- and to try to be as precise as we could
8 with -- so we don't want to confound the results by
9 having a group in there that is using the
10 medications for a legitimate medical purpose.

11 Q. But if you had included the cancer
12 patients in the study, that would have caused a
13 greater number of false positive alarms, correct?

14 A. It could, yes. I am not sure it
15 would, but it could. So I guess you are asking me
16 to project what the results would be.

17 It is potentially true that that
18 would have happened, yes. However --

19 Q. And that is --

20 A. -- keep in mind, the outcome we were
21 trying to predict here is opioid overdose. So they
22 would have -- so it may or may not have. You know,
23 these -- these algorithms are relatively complex,
24 and it may not have come out as an important
25 factor.

1 So I can't speculate. I shouldn't
2 speculate as to whether it would or would not.
3 Because we don't know.

4 Q. Well, but you were involved with the
5 design of the study, and you purposely excluded
6 them because cancer patients often take larger and
7 longer doses of opioids, correct?

8 A. They can take certainly different
9 doses, and they may be on them for a longer period
10 of time.

11 Q. Not just different but the larger
12 doses, right?

13 A. I -- it is beyond my expertise to be
14 able to say that.

15 Q. You also excluded hospice patients
16 for the same reason, right?

17 A. Correct.

18 Q. And in fact, your model identified
19 that seventy-five percent of those individuals
20 receiving an opioid were in a low-risk group with a
21 negligible overdose rate, correct?

22 A. Let me look at that real quick.
23 Would you mind showing me where you are getting
24 that statement from?

25 Q. I think it is mentioned in several

1 different places. One page it is on is Page 10 of
2 the report. Let me see if I can find another for
3 you.

4 So another place you can look is Page
5 6, the Risk Stratification Using Predictive
6 Probability.

7 A. So we do see on Page 10 that Medicare
8 beneficiaries -- so, again, specific to Medicare
9 beneficiaries -- had a -- yeah, yeah. So we say
10 approximately seventy-five percent had a negligible
11 risk of overdose. Yes.

12 Q. And so you would agree that an alert
13 system that would capture that seventy-five percent
14 would contribute to alert fatigue, correct?

15 MR. WEINBERGER: Objection to form.

16 A. I'm not sure how the -- so it gets
17 back to how the alert system is designed. So you
18 need to design the system to take that into -- to
19 take into account whether the patients would fall
20 into those categories. So there's a remaining
21 twenty-five percent --

22 Q. (BY MS. FUMERTON:) Right. So --

23 A. -- remaining twenty-five percent that
24 we have to worry about. So in -- and so let me be
25 clear here, Ms. Fumerton.

1 Alert -- running a program to
2 determine whether a patient is at risk is one
3 thing. Displaying that information or requiring
4 the pharmacist to look at that information as part
5 of the process is another. Right.

6 So the whole premise of my research
7 is to -- is to basically not display alerts when
8 they are not relevant. So when they are not
9 relevant, we don't need to waste the prescriber's
10 time or the pharmacist's time, correct. So that is
11 the whole premise.

12 So it all depends upon what the --
13 what the use was and how -- and how the program was
14 designed to detect that use or misuse as to whether
15 it would be, you know, a good thing or a bad thing.

16 The biggest --

17 Q. But if your report --

18 MR. WEINBERGER: He was in the middle
19 of answering your --

20 MS. FUMERTON: I am not doing it
21 intentionally.

22 MR. WEINBERGER: Well, let him
23 finish. If you know he pauses, then just hold off
24 on your question.

25 A. So with respect --

1 Q. (BY MS. FUMERTON:) Want to go
2 back --

3 A. With respect to alert fatigue, the
4 solution -- as I stated earlier, the solution is
5 not to turn off all alerts or have no alerts. The
6 situation is to make the alerts appropriate for the
7 situation.

8 So, you know, back to your simple
9 suggestion earlier: When the prescription is at
10 24.9 miles, that is not twenty-five miles. But if
11 that was where the pill mill was located, then, you
12 know, it would be relevant to have that --
13 something relevant there to indicate that that was
14 a problem to the pharmacist.

15 So, again, it depends upon how those
16 contextual factors would have played into that
17 particular scenario. You want me to -- to make a
18 general statement that all alerts are bad, and they
19 are not. They are -- or at least I get the sense
20 that you want me to make that statement. My
21 apologies for putting words in your mouth.

22 Q. Yeah, no. Absolutely not.
23 Absolutely not. I am not suggesting in any way
24 shape or form that all alerts are bad.

25 What I am suggesting, based on your

1 research and your statements you have made in your
2 articles, is that if you have a system that alerts
3 seventy-five percent of the time when there's a
4 negligible risk to the individual, that that
5 contributes to alert fatigue.

6 MR. WEINBERGER: Objection.

7 Q. (BY MS. FUMERTON:) And that you
8 should instead be looking for flags that flag only
9 on those individuals that truly are at risk.

10 MR. WEINBERGER: Objection to form.

11 Q. (BY MS. FUMERTON:) Do you agree with
12 that?

13 A. I don't know if seventy-five -- so in
14 this analysis, we looked at overdose risks or a
15 diagnosis of overdose. Is it the only metric to
16 build the rule on? No, it is not.

17 So that number may be -- is likely
18 different than seventy-five percent.

19 Q. (BY MS. FUMERTON:) And it goes back
20 to context, right, of what you said earlier, that
21 you need to understand the context of the
22 situation, the individual patients, the individual
23 locations of the pharmacies, all of that stuff is
24 relevant to this determination of whether or not a
25 particular patient is at risk. Right?

1 A. That is true. That is -- you know,
2 yeah. And --

3 Q. And so -- I mean you used the example
4 in one place twenty-five miles away is nothing.
5 That is what is going to be commonplace for
6 somebody to do, so it would be inappropriate to
7 flag all prescriptions coming more than twenty-five
8 percent [sic] in that instance.

9 If there's another circumstance where
10 the facts are different, then it could be
11 appropriate. But you are not opining one way or
12 the other on what particular metrics would be
13 appropriate for a pharmacy to implement, correct?

14 A. Yes.

15 THE VIDEOGRAPHER: I apologize for
16 the interruption. This is the videographer. I
17 need to have a ten second stop to create a video
18 file.

19 MS. FUMERTON: We have been going for
20 a while. Why don't we take a five -- a ten-minute
21 break. How about that?

22 THE VIDEOGRAPHER: We are off the
23 record at 4:49.

24 MS. FUMERTON: So we will come back
25 at 4:00. Yeah.

1 (Whereupon, a break was had from 4:49
2 p.m. until 5:06 p.m. EDT)

3 THE VIDEOGRAPHER: We are back on the
4 record at 5:06.

5 Q. (BY MS. FUMERTON:) Okay.
6 Dr. Malone, do you have the envelope that is marked
7 Tab 13?

8 A. Yes.
9 (Exhibit 8 was marked for
10 identification.)

11 Q. (BY MS. FUMERTON:) Could you please
12 open that? And for the record, we are going to
13 mark this as Exhibit 8.

14 And also for the record, it is an
15 article entitled "Using Machine Learning to Predict
16 Risk of Incident Opioid Use Disorder Among
17 Fee-for-Service Medicare Beneficiaries: A
18 Prognostic Study."

19 And Dr. Malone, I actually have a
20 really simple question for you on this document,
21 and then we will move on.

22 A. Okay. Go ahead when you are ready.

23 Q. I just wanted to confirm that Exhibit
24 8 is an article that you coauthored, dated July
25 17th, 2020.

1 A. Yes.

2 Q. Okay. Dr. Malone, who asked you --

3 MS. FUMERTON: We can take this one
4 down.

5 Q. (BY MS. FUMERTON:) Dr. Malone, who
6 asked you to be an expert in this matter?

7 A. Mr. Weinberger.

8 Q. When did he ask you to be an expert?

9 A. I think it was the spring. I would
10 imagine somewhere around the last week of March, I
11 believe, somewhere around there. I could look at
12 my calendar.

13 Q. Last week of March?

14 A. Yeah.

15 Q. March 2021?

16 A. Yes, this year, yes.

17 Q. Did you know Mr. Weinberger prior to
18 March 2021?

19 A. I did not.

20 Q. Did he reach out to you?

21 A. Yes, he did.

22 Q. Did he reach out to you with anybody
23 else?

24 A. I believe we had an initial call with
25 one other individual on the line. I don't recall

1 who that was.

2 Q. Do you know if that individual was an
3 attorney?

4 A. I don't know for sure, but I believe
5 so.

6 Q. Do you understand it was an attorney
7 for plaintiffs in this litigation?

8 A. I -- I am assuming it was. But,
9 again, I just had a name. I didn't receive any
10 credentials or anything else from this individual.
11 I guess maybe an email I received at one point.
12 So --

13 Q. Have you been retained by anyone else
14 to provide expert testimony in any opioid-related
15 litigation?

16 A. Several years ago I was asked to
17 be -- to be retained. A firm out of Dallas had
18 contacted me. So there was one meeting and never
19 heard again. And I can't remember what year that
20 was, but several years ago.

21 Q. Did you understand that it had to do
22 with the National Opioid Litigation or something
23 else?

24 A. It had to do with opioid litigation.
25 Whether it was national in scope is another matter.

1 Q. And so you believe you were retained
2 in the last week of March 2021; is that right?

3 A. Let me verify the date, please.

4 Q. What are you accessing?

5 A. My calendar on my phone. I am trying
6 to see if I had a meeting in my calendar. I do not
7 see it. So, again, I think it was about then.

8 Q. And when did you receive the
9 documents that you listed in your report that you
10 relied on for purposes of your testimony?

11 A. Around the first week of April. I
12 was told my report was due the 15th or 16th of
13 April.

14 Q. You are being compensated in this
15 matter at a rate of three hundred eighty dollars
16 per hour, correct?

17 A. That is correct.

18 Q. Are you being compensated at any
19 different amount for testimony?

20 A. This is my only expert testimony.

21 Q. I apologize. Are you only -- my
22 question was unclear.

23 Are you charging only three hundred
24 and eighty dollars per hour -- let me restate that.

25 Are you charging three hundred eighty

1 dollars per hour for all activity in connection
2 with this, or do you have a different rate,
3 depending on what the activity is?

4 A. I am not sure of my agreement with
5 that regard, whether I put a different rate for
6 in-court appearance or not. I think there's a
7 travel rate or I proposed -- I would have to go
8 back and look at those documents. So off the top
9 of my head, I can't recall.

10 Q. Have you submitted any invoices for
11 your work?

12 A. I did not submit an invoice per se in
13 terms of, you know, in a formal -- I submitted a
14 time sheet that had a calculation of hours to date
15 to Mr. Weinberger.

16 Yeah, that was yesterday, I believe.

17 Q. So Mr. Weinberger --

18 A. Maybe the day before. I'm sorry.

19 MS. FUMERTON: We are going to mark
20 as Exhibit 9 a spreadsheet that Mr. Weinberger
21 provided to us, I believe, yesterday.

22 (Exhibit 9 was marked for
23 identification.)

24 A. Okay.

25 Q. (BY MS. FUMERTON:) And so since it

1 was provided yesterday, we didn't have time to send
2 it out to you, but it is just one page and we will
3 put it on the screen.

4 A. Uh-huh.

5 Q. Are you familiar with this document?

6 A. I created that document, yes.

7 Q. Okay. And is this a document that
8 you were just referencing that you provided to
9 Mr. Weinberger that references your time spent on
10 this matter to date?

11 A. It does.

12 Q. And is this an accurate reflection of
13 the time that you spent working on this matter?

14 A. Up through the 20th of May, yes, it
15 does.

16 Q. Okay. And how much time do you think
17 you have spent since May 20th?

18 A. Including today?

19 Q. Not including today because we are
20 not done yet.

21 A. I wish it was. Probably another four
22 hours.

23 Q. And so earlier you testified that you
24 spent seventeen hours reviewing the materials that
25 are listed in your expert report, correct?

1 A. Uh-huh.

2 Q. How long do you estimate that you
3 spent writing the report?

4 A. Somewhere in the neighborhood of two
5 hours. I mean part of it was reviewing the
6 material as I was taking notes and putting together
7 my thoughts. So it is interspersed throughout.

8 Q. Do you still have copies of those
9 notes?

10 A. I do.

11 Q. Did I understand you had four
12 meetings of about two hours each, so eight hours,
13 and that you re-reviewed documents for about
14 another three hours? So I'm not a math major, but
15 that seems to add up more than the nineteen that
16 are listed here.

17 Can you explain that?

18 A. So the three hours you just referred
19 to, you know, are not shown here.

20 Q. Okay.

21 A. So what was the other parts of that?
22 I'm sorry.

23 Q. You said you had four meetings?

24 A. Yeah, not all of those meetings are
25 represented here.

1 Q. Okay.

2 A. Again, it was through the 20th.

3 Q. Right. So two of the meetings were
4 represented here?

5 A. I believe so.

6 Q. So still that would be seventeen
7 hours of reviewing documents, four hours of
8 meetings, two hours to write the report? Something
9 is off with the math, right?

10 A. Well, maybe I didn't state it
11 clearly. So the writing of the report occurred
12 while I was putting those documents together --
13 occurred while I was reviewing the other documents.
14 So the attributes that I was including -- so two
15 hours in terms of, you know, finalizing the report,
16 putting it in the right format, putting it on the
17 right letterhead, etcetera, so --

18 Q. And according to this, the first day
19 you started working on this matter was April 6th,
20 2021; is that accurate?

21 A. That is the first day I started
22 reviewing documents, yes.

23 Q. Did you have staff or anyone else
24 assist you?

25 A. No.

1 Q. Did the University of Utah separately
2 compensate you for your time with this report?

3 A. No.

4 Q. Okay. We can put that document away.
5 Grab your report. I have a couple
6 more questions about specifically what is written
7 in there. So that is Exhibit 1.

8 So I want to flip actually first to
9 the back part of your report, starting on Page 7.
10 And would you agree that the summary of your
11 opinion is that "pharmacy chain organizations
12 created, purchased or aggregated data that could
13 have been used to reduce the inappropriate use of
14 opioids and other medications. The data elements
15 required for the above activities has long resided
16 (since at least 2006 and likely years before that
17 time) within databases, and accumulation of such
18 data across multiple pharmacies permitted the
19 opportunity to inform pharmacists and pharmacy
20 staff to potential illegitimate opioid use"?

21 A. I'm sorry. Your question is, is that
22 an accurate statement? Is that what you are
23 saying?

24 Q. Do you agree that that is a summary
25 of your opinions that you are offering in this

1 matter?

2 A. Yes, it is.

3 Q. And are you offering any other
4 opinion other than that?

5 A. No.

6 Q. If you will flip back to Page 2 of
7 your report. And you talk about issues addressed,
8 and you have seven questions listed here, correct?

9 A. Yes.

10 Q. Who came up with those seven
11 questions?

12 A. Those were derived from the documents
13 I reviewed. So in particular, the CVS SAS program.
14 The questions posed to me are -- posed to me by the
15 plaintiffs' counsel in terms of these attributes,
16 and also the DEA documents I talked about
17 previously about the red flags. So -- and again --

18 Q. We are not sure --

19 A. Yeah, and again, even though I am no
20 longer a pharmacist, you know, the information
21 about, you know, appropriate legitimate use of
22 prescription medications is -- those documents --
23 what constitutes those appropriate use has been
24 available for a long period of time.

25 So I don't recall specifically where

1 that -- where these -- all of these attributes --
2 or where that document is located. But these are
3 things that we are well aware of in the pharmacy
4 community. So these are common knowledge issues.

5 Q. So what did plaintiffs ask you to
6 opine on? I mean you obviously didn't-- to put
7 context in it, just sort of come up with just
8 say -- I am going to issue an opinion on whatever I
9 want.

10 What were you asked to do with
11 respect to --

12 A. Please go to my summary. Please go
13 back to the summary. So the question was whether
14 the organizations, defendants, would have had at
15 their disposal the data that would have then
16 allowed them to create systems to prevent
17 inappropriate use.

18 So in particular, the data elements
19 to do those activities, in terms of identifying
20 these red flags, you know, doctor shopping,
21 pharmacy shopping, inappropriate quantities,
22 inappropriate prescribing by certain medical
23 specialties relative to their peer organizations --
24 peers, using multiple medications concurrently.
25 That is what I was asked to opine on. Could you

1 create systems to reduce the use -- to create
2 flags, create approaches to reduce the use.

3 So my statement "could have been used
4 to reduce the inappropriate use of medications"
5 is -- I saw no evidence that they did use those
6 tools.

7 Q. Okay. So now we are going back to
8 the statement that you said "no evidence that they
9 used those tools," so I guess we are going back
10 there again.

11 Let's start off. I mean you said --
12 let's take Walmart, for example. You looked at the
13 ConnexUs screen shots. Are you familiar with what
14 a patient profile is?

15 A. Yes, ma'am.

16 Q. And that contains lots of information
17 for the pharmacists, correct?

18 A. It does, yes.

19 Q. It contains information about prior
20 fill history?

21 A. Yes.

22 Q. It contains information about where
23 the patient lives?

24 A. It will have the patient's address,
25 yes.

1 Q. And where the patient lives in
2 relation to the pharmacy because the pharmacist
3 knows what pharmacy they are in, right?

4 A. Well, yeah. By deduction, yes, the
5 pharmacist can determine that.

6 Q. Right. And the pharmacist knows
7 where the prescriber is located, right?

8 A. The pharmacy -- well, it depends upon
9 what information is presented on that screen. So
10 physicians do have an office address associated
11 with their DEA registration, so --

12 Q. Is it your opinion that ConnexUs did
13 not show the pharmacist what the address of the
14 prescribers?

15 A. No. I am not -- I am not saying that
16 at all. I am just saying I don't know -- so
17 physicians may practice in different locations. So
18 you are making -- so the statements you are making
19 are overly broad, you know. So there is an address
20 for the prescriber, that is true.

21 Q. Well, I'm sorry. What address
22 information then -- I mean you talk in your report
23 about understanding geospatial analysis, right,
24 which effectively, for those of us who don't have
25 as many fancy degrees, is just where are people in

1 relation to other people, right?

2 A. Yeah, I mean, exactly, that is the
3 basic premise of it. And it is predicated on the
4 data that is in this system. So the data in this
5 system is the registration address used by the
6 doctor associated with it. Where the practitioner
7 actually is when they write the prescription may or
8 may not be at that office.

9 So, you know, I mean, in general, you
10 know, theoretically, somebody would actually
11 practice where their DEA registration is, but that
12 may not be where they wrote the prescription.

13 So you are trying to put a blanket
14 statement -- it appears you are trying to put a
15 blanket statement around the address of the
16 physician when they wrote the prescription, and
17 that information is just not there necessarily.

18 Q. So the pharmacy didn't have that
19 data? I am just trying to understand your
20 position. Did they have that data or they didn't
21 have that data?

22 A. They have the data of the DEA
23 registration, yes.

24 Q. That data also was available to the
25 pharmacist, right?

1 A. Yeah, they have to have that data.
2 They have to have that data.

3 Q. Okay. So understanding the location
4 of the pharmacy, understanding the location of the
5 patient, understanding the location of the doctor,
6 which is all available within ConnexUs, and when a
7 pharmacist is filling out, how are you saying that
8 you saw no evidence that they used those tools?

9 A. The -- let me put it in this context:
10 If you have a car that has a tachometer, does it
11 tell you what speed you're going? No, it tells you
12 how fast the engine is going, right? But yet it is
13 information that is available to you. So you need
14 to transform the tachometer with how the
15 transmission and the wheels so that you can get a
16 speed where you know how fast the vehicle is
17 moving.

18 What I am suggesting is knowing
19 isolated bits of data do not necessarily allow --
20 yes, the pharmacist could sit there and try to do
21 the mental calculations about, okay, where is this
22 patient, how far is this patient from my pharmacy.
23 Do I really know where that address is or do I not
24 know? Okay.

25 You know, so I have to sit there and

1 mentally calculate how many blocks is represented
2 by that address. So for the vast -- for some
3 patients, I shouldn't say vast majority -- for some
4 patients, they get their pharmacies --
5 prescriptions filled within a legitimate area, and
6 they are not pharmacy shopping.

7 But with opioid medications, I think,
8 because even cited in the papers that we have
9 reported, there's a significant increase of the use
10 of these agents.

11 So basically, the guardrails weren't
12 on the system to be able to, at a glance, measure
13 every time, you know -- so every time the
14 pharmacist had to stop and do a calculation, okay,
15 where is this patient relative to my pharmacy,
16 where is this doctor relative to my pharmacy, it
17 required -- you know, it could have been presented
18 in a dashboard format, a distance or, you know --
19 so they would have had to look for that information
20 and assembled it at the same time they are
21 assembling all the other information about the
22 prescription and all the other information about
23 the patient. That is why we do prospective DUR.
24 That patient profile contains lots of drugs.

25 Does the pharmacist know about those

1 drug interactions? They probably know some of
2 them. Do they know all of them off the top of
3 their head? No, they don't. That is why the
4 computer is there to assist them in the process.

5 So the data is there. It is how the
6 data should be used and reported. So that -- my
7 basis is that the data was there. It could have
8 been used to help the pharmacist make a decision,
9 help the pharmacy staff make a decision. So I am
10 not arguing the data is not there, yeah.

11 Q. You are not arguing that the data was
12 not available to the pharmacists either, correct?

13 A. There is data that was not available
14 to the pharmacists. There's no data about how
15 their store rates compared to other stores, how the
16 use of these agents compares to other stores, how
17 that particular prescriber, is that within the
18 normal practice of that prescriber. Do I know
19 every physician within, you know, a geographic
20 location within twenty-five miles and what their
21 normal practice is? No, I don't. I would imagine
22 that most pharmacists would say no, they don't.

23 So what I am advocating for is that
24 there could have been metrics to give the
25 pharmacists information about which prescription --

1 which prescriptions were for legitimate medical
2 purpose and which ones weren't.

3 Q. So you are offering no expert
4 opinions on which prescriptions were for a
5 legitimate medical purpose and which ones weren't,
6 correct?

7 A. That's right.

8 Q. And going back to what we talked
9 about before, you used as an example, you take
10 twenty-five miles. What is more helpful to me as a
11 pharmacist filling a prescription knowing that
12 Sally, who comes in and lives down the street, is
13 filling a prescription, and I can see from the face
14 of it that it was from the Cleveland Clinic -- is
15 that more helpful to me, or is it more helpful to
16 come from geospatial analysis with random figures
17 thrown on it?

18 MR. WEINBERGER: Objection.

19 Q. (BY MS. FUMERTON:) You can -- right,
20 I mean the pharmacist has access to, every time
21 they are filling a prescription, the information
22 that tells them how far away the prescriber is, how
23 far away the patient is? I mean they have that --
24 access to that information as a pharmacist.

25 A. Sure, they could stop and Google --

1 use Google maps or any other program to figure out
2 the distance is what you're suggesting.

3 Q. No. I'm not suggesting that at all.
4 I'm not suggesting that at all.

5 For example, I don't care -- why
6 would it be -- you are sitting here and telling me
7 that it is more relevant the exact mileage that a
8 patient traveled to get to the Cleveland Clinic as
9 opposed to the fact that they went to the Cleveland
10 Clinic?

11 A. No, I'm not telling you that.

12 Q. Right. So then who needs to Google
13 Maps anything? They see on the face of the
14 prescription that it is coming from the Cleveland
15 Clinic. They know, right?

16 A. Presumably, yes.

17 Q. Going back to your seven questions
18 because I do have some specifics about these.

19 A. Okay.

20 Q. You said that you came up with these
21 seven questions on your own, correct?

22 A. No, I did not. As I said, these came
23 from a variety of materials.

24 Q. Okay. Well, where did Question 1
25 come from? "Conduct drug utilization analysis and

1 provide meaningful metrics to assist pharmacists --

2 THE REPORTER: I'm sorry. You are
3 going to have to slow down -- hold on. You are
4 going to have to slow down.

5 Where did Question 1 come from?

6 "Conduct" --

7 Q. (BY MS. FUMERTON:) -- "drug
8 utilization analyses and provide meaningful metrics
9 to assist pharmacists and pharmacy staff to
10 identify and prevent inappropriate use of opioids
11 and other medications, both within and across
12 pharmacies within their organization."

13 A. That particular statement is -- is
14 derived from A, my own knowledge; B, the CVS SAS
15 programs that were provided to me.

16 Q. What is a PDMP?

17 A. Prescription Drug Monitoring Program.

18 Q. And what does the PDMP do?

19 A. Theoretically, it provides a profile
20 for a given patient about how often a certain type
21 of medication has been dispensed for that
22 particular patient. It typically comes from
23 pharmacy organizations or pharmacists or
24 pharmacies, and it allows the pharmacists to
25 determine if that particular individual had had a

1 recent prescription dispensed of a certain class or
2 type as defined by the particular PDMP.

3 Q. And what is the PDMP in the state of
4 Ohio?

5 A. I believe it is called OARRS.

6 Q. And how long has it been in place?

7 A. I'm not sure. I didn't study that.
8 It is beyond my expertise.

9 Q. Do you know how long -- so you are
10 not an expert in the OARRS database or its use,
11 correct?

12 A. No, I am not.

13 Q. And you don't know for how long
14 Walmart pharmacists, for example, have had access
15 to the OARRS database, correct?

16 A. That's correct.

17 Q. And the OARRS database can provide
18 evidence of pharmacy shopping, correct?

19 A. Given that it is the PDMP, it could,
20 yes.

21 Q. And it provides evidence of doctor
22 shopping, correct?

23 A. It could, yes.

24 Q. And, in fact, PDMPs are better than
25 individual pharmacy data because it aggregates

1 information across pharmacies, not just within a
2 particular chain, correct?

3 A. I don't know if I agree with the
4 characterization "better." It contains
5 theoretically more data, if that is what you mean
6 by "better." Because it is -- to your point, it
7 does represent data across multiple pharmacy types,
8 the pharmacy organizations.

9 Q. So you have no opinion on whether or
10 not it would be better for a pharmacist to be able
11 to view whether or not a patient was seeking to
12 fill prescriptions outside their pharmacy chain as
13 opposed to just inside their pharmacy chain?

14 MR. WEINBERGER: Objection, form.

15 A. I don't have an opinion about that
16 particular attribute. I guess what I am trying to
17 get to is how that information presented to the
18 pharmacist can probably, and probably does, matter.
19 And if you allow me to give another analogy, if you
20 want cars to stop at a particular intersection, you
21 put up a stop sign of a certain size. You could
22 also write "stop" in the middle of the road as
23 well. One of these is probably more effective than
24 the other.

25 So I guess my presumption here is

1 that the PDMPs give you a medication profile where
2 you -- with the pharmacist, the pharmacy staff --
3 who knows who actually looked at the data -- would
4 have to scan and make judgments about -- or have to
5 calculate time between fills, amounts, quantities
6 dispensed, etcetera. So a dashboard could have
7 been created that basically said yep, you know, we
8 don't see any -- any flags here, you know.

9 So let's take the situation where the
10 prescription is legitimate, the patient needs the
11 medication, and yet they have had thirty
12 prescriptions over the last year for various
13 medical issues that are in the database.

14 So the pharmacist has to sit there
15 and evaluate that. Okay. And say, you know, what
16 is going on here, you know. That takes time and
17 energy for the pharmacist.

18 On the other hand, if the diagnosis,
19 which is in the pharmacy data or could be in the
20 pharmacy data, is there, combined with that piece
21 of information, it is like oh, this patient is in
22 hospice care.

23 So that information in the PDMP could
24 have been pulled into the pharmacy system, and an
25 alert wouldn't have been generated to the

1 pharmacist about that particular prescription
2 because the patient -- it is for a legitimate
3 medical purpose.

4 The problem was that that data sits
5 there in its raw form with no guardrails, what is
6 appropriate, what is inappropriate, how many
7 milligram -- morphine milligram equivalents is too
8 much. There's no guardrails. It doesn't tell the
9 pharmacist anything about the typical pattern of
10 use for that particular patient or that particular
11 prescriber or that particular diagnosis.

12 All of that data was sitting on
13 defendants' servers. They could have analyzed that
14 and created metrics that said, hey, this
15 prescription exceeds a five percent threshold.
16 And, in fact, there are documents that these
17 organizations had actually created those metrics.
18 It is like oh, this is a five percent threshold or
19 here is the two percent threshold.

20 And the paper that was published in
21 the New England Journal of Medicine, they
22 identified -- if I may refer back to that document,
23 they identified, as they stated -- so this is
24 Exhibit 3 -- we identified --

25 Q. (BY MS. FUMERTON:) Hopefully, you

1 are going to be able to answer my question at this
2 point.

3 A. I guess what I am saying is, you
4 asked the question, you know, would the PDMP data
5 be useful. And I am saying, yeah, it is useful,
6 but it is not the most useful data that could have
7 been provided to the pharmacist or the pharmacy
8 staff.

9 You know, my argument is with respect
10 to Number 1, which is what you asked me about, your
11 question, is conduct meaningful drug utilization
12 providing meaningful metrics to assist the
13 pharmacist and pharmacy staff.

14 The PDMP provides generally -- again,
15 I'm not an expert on the OARRS system -- may or may
16 not have provided meaningful metrics to the
17 pharmacists.

18 MR. SWANSON: This is Brian Swanson
19 for Walgreens. I move to strike as nonresponsive.

20 Q. (BY MS. FUMERTON:) Okay. There's a
21 lot thrown out there. So we would respectfully
22 ask, just so that we don't need to go beyond, to
23 try to restrict your answers to the questions I am
24 asking.

25 A. Okay.

1 Q. You make a comment -- I will sort of
2 go back through them.

3 You said, for example, there might be
4 a five percent threshold and that will tell you
5 whether you are seeing a five percent threshold.
6 Okay. So what does that tell you about whether or
7 not that prescription is appropriate or not?

8 A. That piece of information in and of
9 itself doesn't, but it -- but it gives the
10 pharmacists -- so if it does exceed the five
11 percent threshold, it gives the pharmacist the
12 opportunity to investigate more. So we do this
13 with drug interaction warnings.

14 So we have moderate, severe,
15 contraindicated in some systems. So if the warning
16 comes back moderate, the pharmacist, you know,
17 should, you know, consider, you know, what is going
18 on with the patient, how long have they been on it,
19 what is the dose of the medication, what is the
20 route, what is the strength, what are the
21 directions for use.

22 So prospective drug utilization
23 programs are designed to assist the decision-making
24 of the pharmacist. Does the pharmacist need to
25 know there's been five case reports associated with

1 that drug interaction, and of those five case
2 reports, three patients ended up in the hospital?
3 Typically that level of detail isn't there.

4 But with the PDMPs -- some PDMPs do.
5 And, again, I'm not familiar with OARRS system.
6 But what some of those systems do, they provided a
7 listing just like the patient profile that didn't
8 give any sense to how the data should be
9 interpreted, so --

10 Q. Okay. Again, I am going to strike as
11 nonresponsive because, frankly, you don't know what
12 OARRS does or does not do, right? So you are not
13 offering any opinion whatsoever as to whether or
14 not OARRS actually provided this information of
15 your seven questions that you thought the
16 pharmacists should have access to, right?

17 MR. WEINBERGER: Objection. Earlier
18 you asked him to compare OARRS to what the -- the
19 proposed system that he would have suggested that
20 these defendants could have utilized.

21 So you have asked him about OARRS.
22 He said he didn't know what OARRS did, and then you
23 asked him to compare the two.

24 MS. FUMERTON: Exactly. No, I
25 didn't. So you know, I didn't do that at all. He

1 went on to talk about some other random state or
2 hypothetical -- that is the problem here, right. I
3 mean, technically, this entire report is based on
4 hypotheticals.

5 THE REPORTER: I can't understand
6 you. Hold on. Hold on. I can't understand you.
7 "Exactly. No, I didn't at all. He went on to talk
8 about some other random" --

9 MS. FUMERTON: PDMP. He has
10 testified he does not know anything about what
11 OARRS can and cannot do. Full stop.

12 A. And you --

13 MS. FUMERTON: So I am just saying
14 having him testify about what some hypothetical
15 other PDMP might do is completely irrelevant to
16 this case, and that is why it is completely
17 nonresponsive to my question, and I am going to
18 move to strike it.

19 Q. (BY MS. FUMERTON:) But going back to
20 this dashboard, again, you can't point to any
21 examples of this dashboard ever being utilized in
22 practice that has all of these elements that you
23 describe, correct?

24 A. That is correct.

25 Q. With respect to the dashboard, this

1 hypothetical dashboard that you have created, at
2 the end of the day, that is not going to tell you
3 whether or not the prescription is appropriate or
4 inappropriate, even if it could exist, correct?

5 A. That is correct.

6 Q. It is the pharmacist's judgment,
7 assessing the totality of the circumstances, to
8 make a determination as to whether, in their
9 professional judgment, they view that the
10 prescription is appropriate to fill, correct?

11 A. State that last part. I'm sorry. It
12 broke up.

13 Q. At the end of the day, it is the
14 pharmacist who has to make the professional
15 judgment, assessing the totality of the
16 circumstances, as to whether or not it is
17 appropriate to fill the prescription?

18 A. Yes, pharmacists have that
19 responsibility.

20 Q. And --

21 A. But I guess I would add to that, as
22 it applies to drug interactions, and other data --
23 we see dangerous combinations dispensed to patients
24 all the time, even though these systems -- even
25 though, I should say, some systems are probably in

1 place.

2 But I guess the point I would make is
3 that these systems have heretofore largely not
4 assisted the pharmacists in a meaningful way is
5 kind of my preposition here. Is that --

6 Q. So you are saying that the DUR
7 systems do not assist the pharmacists in a
8 meaningful way?

9 A. In some instances. Depends upon the
10 situation. But in some instances they don't seem
11 to help the pharmacists at all.

12 Q. And do you understand what alerts
13 Walmart had in place for its DUR system?

14 A. No, I don't. I know generally what
15 alerts are in place in pharmacy practice, but what
16 specific alerts Walmart was using, no, I am not
17 aware of all of those.

18 Q. Are you aware of whether or not
19 Walmart tailored specific alerts to its system?

20 A. No, I am not aware.

21 Q. In your opinion, you said that
22 pharmacies should do that, right?

23 A. State the question again. In my
24 opinion what?

25 Q. In your report you state that

1 pharmacies should request specific -- I take it
2 back.

3 You are not offering any opinions
4 about what they should have done. But they could
5 have asked --

6 A. They could have asked --

7 THE REPORTER: Hold on. Y'all talked
8 over each other.

9 Q. (BY MS. FUMERTON:) I will rephrase
10 the question.

11 In your report, you state that
12 pharmacies could have requested edits to
13 off-the-shelf programs that Medi-Span, for example,
14 provides, correct?

15 A. Where am I saying that? I'm sorry.
16 I want to make sure I am --

17 Q. So if you look on Page 7 of your
18 report, at the bottom of the page, the bottom of
19 the middle paragraph, you say, "Finally,
20 pharmaceutical organizations could have requested
21 such algorithms be included in Medi-Span or other
22 drug knowledge data vendors," correct?

23 A. Yes. As purchasers of those, yes,
24 they could have asked those organizations to create
25 algorithms, especially as it relates to in -- in

1 this specifically, to Medi-Span and/or First
2 Databank. You know, algorithms for drug
3 interactions, or two drugs, multidrug combinations
4 could have been requested. I saw no evidence that
5 those had been requested by the -- by the pharmacy
6 organizations.

7 Q. Plaintiffs didn't provide that to
8 you, right?

9 A. I'm sorry?

10 Q. I said plaintiffs didn't provide that
11 to you, right?

12 A. I don't know.

13 Q. Well, would it be relevant to your
14 opinion if there were documents that showed that
15 those requests were made?

16 A. Sure, it would.

17 Q. And you mentioned stuff about
18 algorithms based on days' supply or early refill
19 notifications. Are you aware of whether or not
20 Walmart did that?

21 A. No.

22 Q. So you don't know what Walmart did
23 provide to its pharmacists, correct?

24 A. Beyond what was provided to me, no, I
25 am not aware what was in their computer system.

1 Q. Are you aware of what is in the
2 computer system of any of the other defendants,
3 other than what is specifically mentioned in your
4 report?

5 A. The -- I am just going to make sure I
6 am making my statement correct here. I had no
7 evidence that they provided any of the content
8 associated with those -- go to Page -- I'm sorry,
9 Page 7 -- no, I'm sorry. Where am I getting -- key
10 questions page. I guess this is Page 3. Well,
11 Page 2.

12 Starting on Page 2. So I didn't see
13 any evidence beyond -- that this was provided to
14 pharmacists in a summarized manner. So if it
15 exists, I have not seen it.

16 Q. Your second question is, was it
17 possible, using data available to chain pharmacy
18 organizations, to provide pharmacists with alert
19 warnings about overprescribing by certain licensed
20 subscribers, correct?

21 A. Yeah.

22 Q. And you have no opinion, though, as
23 to what overprescribing is, correct?

24 A. The definition of what would
25 constitute overprescribing would probably vary by

1 medical speciality. But no, I don't have a defined
2 number if you are looking for that number.

3 Q. For number three you say, "Detect
4 inappropriate prescribing and consumption using
5 geospatial data analysis." And again, we have
6 established that is just where the pharmacy is
7 located, where the patient is located and where the
8 prescriber is located, right?

9 A. That is correct.

10 Q. Number four, "Detect excessive dose
11 and quantity, accounting for prescriber specialty
12 and practice," correct?

13 A. Again, that is what the document
14 says, yes.

15 Q. Well, that is what you wrote, right?

16 A. And that is what I wrote, yes.

17 Q. Okay. And you are not offering any
18 opinions as to what is an acceptable dose or
19 quantity for a particular prescriber specialty,
20 correct?

21 A. That's right.

22 Q. And Number 5 is "Identify potential
23 pharmacy shopping by consumers seeking opioids and
24 other medications," correct?

25 A. Yes.

1 Q. And you don't know what OARRS
2 provided, but if OARRS did provide information to
3 pharmacies about whether patients were visiting
4 multiple pharmacies, that would provide this
5 information, correct?

6 A. It could provide it, yes.

7 Q. Are you aware of any attempts to do a
8 national PDMP?

9 A. I haven't followed the issue that
10 closely, no.

11 Q. Do you think it would be useful to
12 have a national PDMP?

13 A. Insomuch with adjoining states --
14 let's take for example Southern Ohio where you have
15 Kentucky and across the border from Cincinnati,
16 and, you know, if you had two different systems
17 operating on that border, that would be, you
18 know -- or defined by that border, that makes it
19 very challenging for a pharmacist in one state to
20 be able to ascertain what is going on in the other
21 state, even though the geographic distance is
22 relatively close.

23 So -- so I could imagine in those
24 situations that might be useful.

25 Q. Number 6 is "Identify use of drug

1 combinations, so-called 'Holy Trinity,' using
2 pharmacy data," correct?

3 A. Yes.

4 Q. And each of the pharmacies' DUR
5 systems that were in place actually did identify
6 drug combinations, correct?

7 THE REPORTER: Actually did identify
8 drug --

9 MS. FUMERTON: Combinations.

10 MR. WEINBERGER: Objection, form.

11 A. Based upon the depositions of the
12 representatives from the individuals that appeared
13 that they all used Medi-Span or First Databank,
14 which would be able to identify drug interactions.
15 I am not aware of First Databank or Medi-Span
16 having -- in the time frame we are talking about
17 having -- having this Holy Trinity as a part of the
18 program.

19 Q. (BY MS. FUMERTON:) What is the Holy
20 Trinity?

21 A. It is the medications you referred to
22 earlier, right? So opioid, a muscle relaxant, a
23 benzodiazepine.

24 Q. Are you offering an expert opinion as
25 to whether or not those medications are

1 contraindicated?

2 A. No. I didn't come up with -- I
3 didn't come up with the name.

4 Q. Are you offering an expert opinion as
5 to whether it is appropriate for those medications
6 to be dispensed to the same patient?

7 A. Nope.

8 Q. Number 7 is "Detect overuse through
9 early refills or new prescriptions," correct?

10 A. Yes.

11 Q. Is it your opinion -- well, are you
12 aware that Walmart had a system in place to detect
13 early refill?

14 A. I am aware that they had -- they had
15 that within the store, yes.

16 Q. So when you say that the tools
17 weren't given to the pharmacists, this was a tool
18 that was given to the pharmacy, right?

19 MR. WEINBERGER: Objection.

20 A. The screen shot that I saw, there was
21 a warning about an early refill, what have you. I
22 don't know the algorithm behind that.

23 Q. (BY MS. FUMERTON:) Well, you said
24 earlier that you saw no evidence that these tools
25 were provided to the pharmacist, so that is not a

1 true statement, right?

2 MR. WEINBERGER: Objection, form.

3 Q. (BY MS. FUMERTON:) You did see
4 evidence that at least some of these tools were
5 provided to the pharmacists?

6 MR. WEINBERGER: Objection, form.

7 A. The -- I guess the -- the context
8 that I should have added to that statement -- and I
9 apologize that I didn't put it in there -- within a
10 store, we know that we can detect early refills.
11 And that is common pharmacy knowledge.

12 What I should have added to that
13 statement was early refills, getting it from, you
14 know, other pharmacies within the chain. So I -- I
15 don't know if that was available or not.

16 Q. (BY MS. FUMERTON:) The PDMP shows
17 that, right?

18 MR. WEINBERGER: Objection, form.

19 A. It may, yes.

20 Q. (BY MS. FUMERTON:) So you -- so that
21 I understand a little bit how you did your report.
22 So you asked these seven questions, but I don't see
23 seven answers.

24 So if you look to then your
25 evaluation of the key questions, it looks like you

1 have it divided into two sections, the first one
2 being drug utilization review of prescription
3 level, correct? Page 4?

4 MR. WEINBERGER: Objection to the
5 comments. Go ahead.

6 A. I'm sorry. Could you repeat the
7 question?

8 Q. (BY MS. FUMERTON:) Sure. You asked
9 seven questions or you identified seven key
10 questions, correct?

11 A. I did.

12 Q. And then you have an evaluation of
13 the key questions, correct?

14 A. I do, yes.

15 Q. And you didn't divide it up into
16 seven different sections, correct?

17 A. No, I did not, no.

18 Q. Okay. So looking at the first one,
19 you have drug utilization review at the
20 prescription level, correct? And I am looking at
21 Page 4.

22 A. Uh-huh.

23 Q. You have a semicolon -- sorry, you
24 have a colon. And so that answers the first key
25 question that you had. Correct?

1 A. Well, it -- it actually could answer
2 more than that. So that paragraph that starts on
3 the bottom of Page 4 and continues on to the top of
4 Page 5 addresses drug utilization, addresses part
5 of Question 2, addresses Question 4 and addresses
6 Question 6.

7 Q. So if you look on Page 5, you have a
8 statement that says, "However, these vendors don't
9 provide warnings based on aggregate prescription
10 use or at the prescriber level." Do you see that?

11 A. Please highlight it, if you don't
12 mind, Kristin.

13 Q. (BY MS. FUMERTON:) Just at the top
14 of Page 5. It says --

15 A. I found it. Yes, I did find it.
16 Thank you.

17 Q. Are you familiar with duplicative
18 therapy warnings?

19 A. Oh, yeah, I am, yes. That is not
20 what I was -- no, I am not referring to duplicative
21 therapy here.

22 Q. What are you referring to?

23 A. So the drug knowledge database
24 vendors focus at the drug and the patient level.
25 They don't integrate prescriber information.

1 Q. I am not following. How is
2 that aggregate prescription use?

3 You say, "These vendors don't provide
4 warnings based on aggregate prescription use."
5 They do do that, right?

6 A. So I guess we could dither about the
7 definition of "aggregate prescription" use. With
8 aggregate prescription use, I was referring to the
9 concept of across patients, not within patients.
10 So Medi-Span and First Databank focus at the within
11 patient level.

12 So this comment refers to aggregation
13 across patients within a store, within -- by a
14 provider or by a provider specialty or by a medical
15 diagnosis.

16 Q. So let's say that you have a
17 prescriber, and ninety percent of the prescriptions
18 they write are opioids. Does that tell you the
19 prescription is inappropriate?

20 A. Not necessarily.

21 Q. Does it tell you it is appropriate?

22 A. Not necessarily.

23 Q. It doesn't tell you one way or the
24 other, right?

25 A. It can give -- well, my premise is it

1 can give you a measure of whether it would be
2 appropriate or inappropriate.

3 Q. And a pharmacist must assess still
4 whether or not that information is appropriate,
5 correct?

6 A. That is true, yes.

7 Q. Next you have "creating opioid
8 specific red flags." Do you see that?

9 A. Uh-huh.

10 Q. Were you asked to assume that any
11 particular attributes were red flags?

12 A. Yes, I have -- well, I guess I
13 interpreted that based upon my own understanding of
14 the problem of opioid use. I am sorry if I --
15 would you restate that question to make sure I
16 answered it correctly?

17 Q. Were you asked to assume that any
18 particular attributes were red flags for purposes
19 of your opinion?

20 A. Was I asked to assume? I don't
21 know -- no, I was not asked to assume. These are
22 attributes that, in the pharmacy profession, we are
23 well aware of them.

24 Q. Do you agree with the statement that
25 most DUR warnings are, therefore, not relevant to

1 inappropriate opioid use?

2 A. I am sure -- I am not sure your
3 question -- could you restate?

4 Q. Do you agree that most DUR warnings
5 are not relevant to inappropriate opioid use?

6 A. I don't have any data to -- well,
7 thank you.

8 This is probably true, yes.

9 Q. You wrote it in your report, correct?

10 A. This is true, yes. Yes. I am sorry.
11 I was putting it in a broader context.

12 So, yeah, so the warnings generated
13 by First Databank and Medi-Span do not assess the
14 appropriateness of opiate use.

15 Q. Yes.

16 A. I'm sorry. We went between
17 paragraphs there, so my train of thought was mixed
18 up.

19 MR. WEINBERGER: Been a long day.

20 Q. (BY MS. FUMERTON:) Well, in fact --
21 but the dashboards that you are talking about don't
22 identify inappropriate prescription use either,
23 right?

24 A. I am not sure what right you are
25 referring to. So the dashboard what?

1 Q. The dashboards, these dashboards that
2 you have talked about that nobody has ever
3 implemented --

4 A. Uh-huh.

5 Q. -- they don't identify inappropriate
6 prescription use either, correct?

7 MR. WEINBERGER: Objection, form.

8 A. No. I can't say that. So when you
9 say inappropriate -- are you saying inappropriate
10 opioid use or inappropriate use?

11 Q. (BY MS. FUMERTON:) It is your
12 dashboard. Which one --

13 A. You are suggesting -- okay. Again,
14 making sure I understand your question.

15 So you are suggesting what they could
16 have done versus what they have?

17 MR. WEINBERGER: Objection.

18 A. I'm sorry.

19 Q. (BY MS. FUMERTON:) Well, we know
20 these dashboards don't exist in practice, right,
21 nobody has done it before?

22 A. Well, DUR --

23 Q. But hypothetically, you said --

24 MR. WEINBERGER: Can we -- let's just
25 slow down. Let her ask the question and listen to

1 the question, and then answer it, okay? I realize
2 it is late in the day, so we are getting all
3 confused.

4 MS. FUMERTON: I'm not confused at
5 all.

6 Q. (BY MS. FUMERTON:) But with respect
7 to the dashboards that you are saying could have
8 been created, those don't identify inappropriate
9 opioid use either, correct?

10 A. No. That is not correct. They
11 could.

12 Q. So the dashboard itself will tell you
13 whether or not the appropriate -- the opioid use is
14 appropriate or inappropriate?

15 A. Oh, I -- now I understand your
16 question. The dashboard would give you a sense or
17 degree that this may or may not be a problem
18 prescription. Is it going to be --

19 MS. FUMERTON: Why don't we take a
20 break.

21 A. Is it going to be definitive? No.
22 It is not going to be definitive.

23 MR. WEINBERGER: Okay.

24 MS. FUMERTON: Why don't we take a
25 break, and I will look at my notes to see if we --

1 to see what more I may or may not have. You want
2 to take a ten-minute break?

3 THE VIDEOGRAPHER: Okay. We will go
4 off the record at 6:11.

5 (Off-the-record discussion.)

6 (Whereupon, a break was had from 6:11
7 p.m. until 6:20 p.m. EDT)

8 THE VIDEOGRAPHER: We are back on the
9 record at 6:21.

10 MS. FUMERTON: Dr. Malone, thank you
11 for your time today. I don't have any further
12 questions, subject to any redirect that
13 Mr. Weinberger might ask you. But I know that
14 Mr. Kobrin has some questions for you, so I am
15 going to go off the video now. Thank you very
16 much.

17

18

19 EXAMINATION BY MR. KOBRIN:

20 Q. Hey, Dr. Malone, my name is Josh
21 Kobrin. I am from the law firm of Marcus &
22 Shapira. We represent Giant Eagle, and I just have
23 a handful of quick questions for you. I don't mean
24 to drag this out.

25 I just want to go back a little

1 earlier in the day we talked about the size of the
2 productions in this case and that you spent
3 approximately seventeen hours reviewing documents.
4 Do you recall that conversation?

5 A. Yes, I do.

6 Q. And I don't mean to go back through
7 that at all. I just wanted to have context for the
8 questions I just had on follow-up.

9 Among the Giant Eagle documents, by
10 that I mean the documents that Giant Eagle produced
11 from its business records in this litigation, you
12 looked at a total of four of those Giant Eagle
13 documents in preparation for your expert report.
14 That is correct, right?

15 A. Just like the others, the testimony
16 from Lynn Shirk, and there may have been exhibits
17 associated with that folder. And --

18 Q. Uh-huh. I'm sorry. Did you say the
19 testimony of -- you are referring to the
20 Christopher Miller testimony?

21 A. No. I believe the name I had on here
22 was Lynn Shirk.

23 Okay. I'm looking at the wrong -- my
24 bad. Okay. Now we are down to it.

25 Q. You were looking at Rite Aid, right?

1 Rite Aid was right under there.

2 A. Yes, I am. So exhibits that would
3 have been in that folder or subfolder would have
4 been the documents I looked at.

5 Q. And I will represent to you that
6 there were only actually two documents that were
7 exhibits to the Christopher Miller deposition that
8 were produced by Giant Eagle. So taking those two,
9 as well as the other two that you reference under
10 Giant Eagle on this page of your report, which is
11 Page 4, you looked at a total of four documents
12 produced by Giant Eagle in preparation for your
13 report, correct?

14 A. I believe so.

15 Q. And none of those documents had any
16 information about how Giant Eagle pharmacists used
17 the patient profile in their system, did they?

18 A. I didn't see anything, no, sir.

19 Q. And none of those documents had any
20 information about how Giant Eagle pharmacists used
21 the OARRS PDMP system from the State of Ohio,
22 correct?

23 A. That is correct.

24 Q. And none of those documents had any
25 information about how Giant Eagle analyzes

1 dispensing data, correct?

2 A. I don't recall any information
3 associated with that, no.

4 Q. And you didn't see any dispensing
5 guidelines that were part of Giant Eagle's
6 production, correct?

7 A. So the DUR screens may have contained
8 information about -- so may contain things that may
9 be considered dispensing guidelines, but I don't
10 recall anything that said specifically dispensing
11 guidelines for using -- or for dispensing these
12 medications or those medications, no, I don't
13 recall that.

14 Q. The only thing you recall is an
15 example of a DUR screen; is that what you are
16 saying?

17 A. Yes.

18 Q. So you knew they had a DUR system?

19 A. Yes, I did.

20 Q. But you didn't see any dispensing
21 guideline created by Giant Eagle?

22 A. I did not.

23 Q. You didn't see any dispensing
24 policies created by Giant Eagle?

25 A. I did not.

1 Q. And you didn't see any dispensing
2 procedures or procedure documents created by Giant
3 Eagle?

4 A. I did not.

5 Q. Did you at any point ask counsel for
6 the plaintiffs in this case whether those documents
7 existed?

8 A. No. Those are outside the scope of
9 my -- no, I did not.

10 Q. Are you saying that those documents
11 had no relevance to your report?

12 A. To the question about whether the
13 systems were in place to create the data that I was
14 suggesting? Those documents weren't relevant to
15 that report.

16 Q. So any dispensing procedures,
17 policies or guidelines have no relevance to whether
18 these systems were in place at Giant Eagle?

19 A. I can't answer that question, whether
20 they have no relevance. They have no relevance to
21 my report, yes, no relevance to my report.

22 Q. So whether there were guidelines,
23 policies and procedures have no relevance to your
24 report?

25 A. That's correct.

1 Q. Any work I believe -- well, I don't
2 want to say -- you have worked at I know pharmacies
3 in the past. Have you ever been behind the counter
4 at a Giant Eagle pharmacy?

5 A. No, sir.

6 Q. Have you ever been in a Giant Eagle?

7 A. No, sir.

8 Q. Do you know what a Giant Eagle is?

9 A. I really don't, no. Whether it is a
10 stand-alone pharmacy or whether it is a grocery
11 store pharmacy or -- you know, what -- what you
12 have for a front end or what you have for a back
13 end, no.

14 Q. You have no idea?

15 A. I'm not aware of it, no.

16 Q. Did you ever ask plaintiffs' counsel
17 for any additional information about the defendants
18 in this case?

19 A. I did not, no.

20 Q. Do you know how the computer -- do
21 you know how the computer servers worked at Giant
22 Eagle's retail locations?

23 A. Through the deposition, there was
24 some information about that. It was fairly
25 cursory. So I wouldn't say I have an intimate

1 knowledge of that data system, but it appeared that
2 those -- based upon what that -- the responses to
3 the -- contained within the deposition, it appeared
4 that there was some coordination of that data
5 across the systems, not necessarily live but
6 aggregated either at the end of the day or at some
7 time during the day.

8 Q. Do you have enough information to
9 understand how they work?

10 A. I believe so.

11 Q. Do you have enough information -- do
12 you have enough information to understand how Giant
13 Eagle's centralized computer services work?

14 A. Well, your definition of work may be
15 an issue here. So what do you mean by "work"?

16 Q. How they function, how they collect
17 data, how they analyze data, how they back up data.

18 A. I did not see any documents
19 associated with those activities.

20 Q. Were the computer servers at Giant
21 Eagle's retail locations -- now that we have kind
22 of clarified what "work" means, do you have enough
23 information to understand how they gather data,
24 assess data, back up data, analyze data, store
25 data?

1 A. There was some information about how
2 they put those data sets together.

3 Q. Which data sets are you talking
4 about?

5 A. Well, prescription record data, as it
6 appeared that that information was transferred to
7 that central facility or their servers or whatever
8 they have. And I think there was reference to an
9 off-site data server as well.

10 But the details of that were not
11 provided in that document.

12 Q. All right.

13 A. And --

14 Q. Do you feel like you have enough
15 understanding of how they worked to have an expert
16 opinion on it?

17 A. An expert opinion as respect to the
18 materials that I produced, yes.

19 Q. As to your report, describing an
20 expert opinion on how the servers work?

21 A. I made no statement or assertions
22 about how the servers work in my report.

23 Q. So you don't have an expert opinion
24 on how the computer systems at Giant Eagle work?

25 A. No, I don't.

1 Q. Okay. Do you have an expert or -- do
2 you know enough about the technological
3 capabilities of Giant Eagle's computer systems to
4 have an expert opinion on that?

5 A. Restate the question. I want to make
6 sure I understand.

7 Q. Do you have enough information about
8 the technological capabilities at Giant Eagle to
9 have an expert opinion as to that?

10 A. That is a very broad question. I
11 would say some attributes I probably have enough
12 information. Other attributes, I probably don't.

13 Q. So you are not --

14 A. I am not asserting that I am fully
15 and completely informed about Giant Eagle's
16 processes and computer systems.

17 Q. Are you expressing an expert opinion
18 as to Giant Eagle's technological capabilities,
19 computer systems and processes in your expert
20 report?

21 A. No, I am not.

22 Q. Not at all?

23 A. Not specific to Giant Eagle, no.

24 Q. Okay.

25 MR. KOBRIN: All right. I am good.

1 I don't know if any of my other co-defendants have
2 a couple of questions for you as well. I will pass
3 to them, and if they don't, I will pass the
4 witness.

5 Does anyone else have any questions?

6 MR. SWANSON: Nothing for Walgreens,
7 thank you.

8 MR. KOBRIN: Pete, you are muted.

9 MR. WEINBERGER: I am ready to do
10 some questioning unless there are questions from
11 any of the other defendants. All right.

12

13 EXAMINATION BY MR. WEINBERGER:

14 Q. Dr. Malone, I have got a few
15 questions to ask you. You have been patient. Just
16 a few more questions, and then there may be some
17 questions as a result of my questions.

18 So I want you to pull out Exhibit
19 Number 9, please. Sorry, Exhibit 7, which was the
20 journal article that you coauthored entitled
21 "Evaluation of Machine Learning Algorithms For
22 Predicting Opioid Overdose Risks," if you can pull
23 it out.

24 A. Okay.

25 Q. Got it in front of you?

1 A. I do.

2 Q. Okay. So if this -- is it true that
3 this study was of Medicare beneficiaries?

4 A. I am just going to make sure -- we
5 have done some work together with our data sets, so
6 I'm going to make sure that this -- yes, this is
7 the Medicare beneficiaries, yes.

8 Q. Right. And if you go down to the
9 Results section, it says that the beneficiaries had
10 similar characteristics, meaning SD age,
11 sixty-eight. Does that mean that the sample size
12 or the sample had an age mean of sixty-eight years
13 old?

14 MS. FUMERTON: Objection, form.

15 Q. (BY MR. WEINBERGER:) See under
16 Results, just in the first page, under Results.

17 MS. FUMERTON: Objection, leading.

18 Q. (BY MR. WEINBERGER:) First sentence?

19 A. Yes, the mean age with standard
20 deviation was sixty-eight with a standard deviation
21 variance of 14.5 years.

22 Q. So if this was a study that was
23 looking at data from Medicare patients, one would
24 assume this would be an older population, right?

25 MS. FUMERTON: Object to the form.

1 Objection, leading.

2 A. Medicare provides benefits to both
3 older adults and disabled adults. And let me look
4 real quick in the Methods here to determine if
5 there was any other --

6 (Pause.)

7 A. So the sample is limited to Medicare
8 beneficiaries between January 1st, 2011 and
9 December 31st, 2015. This is under the Methods
10 design sample. These were fee-for-service adult
11 beneficiaries, so we don't include any children.
12 Did not have cancer and received one or more
13 prescriptions during the study period.

14 So it could include Medicare
15 beneficiaries who qualify for Medicare due to a
16 disability under the Social Security
17 Administration's definition of disability.

18 Q. (BY MR. WEINBERGER:) With a mean age
19 of sixty-eight in terms of this group of patients,
20 would you agree that that is an elderly portion of
21 the population generally?

22 A. Yes, I would.

23 MS. FUMERTON: Object to the form.

24 Q. (BY MR. WEINBERGER:) And you know,
25 you were asked earlier by Ms. Fumerton about the

1 twenty-five percent were at risk, the seventy-five
2 percent were not at risk. You recall that
3 questioning?

4 A. Uh-huh.

5 Q. Yes?

6 MS. FUMERTON: Objection, form.

7 A. I do.

8 Q. (BY MR. WEINBERGER:) Okay. So is
9 this sample of patients, from your perspective,
10 representative of patients in our population that
11 utilize or are prescribed opioids?

12 MS. FUMERTON: Objection, form.

13 Q. (BY MR. WEINBERGER:) In terms of age
14 group?

15 A. By definition, the Medicare sample is
16 a limited sample of the population. So through
17 inference, it is not the totality of individuals
18 that would receive an opioid medication, by a long
19 way.

20 Q. So is it fair or not to use the kinds
21 of percentages that Ms. Fumerton used in terms of
22 applying that to opioid risk of overdose in the
23 general population?

24 A. The study --

25 MS. FUMERTON: Object to the form.

1 A. My apologies. The study only applies
2 to the Medicare beneficiaries that were in the
3 study. So it can't be inferred that this applies
4 across all populations.

5 Q. (BY MR. WEINBERGER:) Or across the
6 population in general that is prescribed and uses
7 opioid prescriptions, right?

8 A. That is correct.

9 MS. FUMERTON: Objection to the form.

10 Q. (BY MR. WEINBERGER:) Now, you were
11 asked some questions about -- let me go to your
12 report. So pull out Exhibit 2, please.

13 A. Okay.

14 Q. Exhibit 1, sorry.

15 A. Oh, yeah.

16 Q. So at the top of Page 2 of your
17 report, if you would pull that out.

18 A. Okay.

19 Q. You describe your twenty years
20 studying the issue of drug-drug interactions, do
21 you see that?

22 A. Yes, I do.

23 Q. Just read that paragraph to yourself
24 for a moment, please.

25 A. Okay.

1 Q. So with respect to your research on
2 drug-drug interactions, have you become familiar
3 with dispensing data and how dispensing data is
4 stored at pharmacies over a number of years?

5 MS. FUMERTON: Object to the form.

6 A. Yes, I am. Yes, I am.

7 Q. (BY MR. WEINBERGER:) And have you --
8 and so you have -- you have used that information,
9 then, as part of your research?

10 A. Yes. Yes, I have.

11 MS. FUMERTON: Objection to the form.

12 Q. (BY MR. WEINBERGER:) And how is it
13 then that you have used data, dispensing data, with
14 respect to studying drug-drug interactions, and
15 coming up with answers to issues like how one warns
16 about potential interactions?

17 MS. FUMERTON: Objection, form.

18 A. So the -- the length that we have
19 tried to establish in the literature through our
20 research is -- is using data from -- from
21 pharmacies and other information about those drug
22 interactions and demonstrating that -- that there
23 is many drug interactions that get through the
24 system and are not prevented, and then trying to
25 provide ways to change those systems, such that

1 they provide useful information to the pharmacist
2 and the pharmacy staff.

3 Q. (BY MR. WEINBERGER:) So have you
4 created, either yourself or with colleagues,
5 software -- software algorithms using dispensing
6 data to create alert systems for use at pharmacies
7 or in the healthcare field?

8 A. Yes, we have.

9 MS. FUMERTON: Objection, form.

10 Q. (BY MR. WEINBERGER:) And is -- so in
11 terms of your expertise and experience, what is
12 the -- what is the methodology that you utilize in
13 order to create the software algorithms, just
14 generally speaking? What is the methodology that
15 you use?

16 A. The --

17 MS. FUMERTON: Objection, form.

18 A. The general approach is that we
19 use -- you know, we are usually evaluating specific
20 drug combinations, so we need to be able to
21 identify the unique drug agents, and that is done
22 via a variety of therapeutic classification systems
23 and also ways to represent those -- those drug
24 products.

25 So every drug product dispensing at

1 its state is linked to a National Drug Code. That
2 National Drug Code is used as part of the process
3 of filling the prescription and typically submitted
4 to third party payors, via the NCPDP
5 Telecommunications Standard. I will clarify that.
6 It was not the Script Standard, the
7 Telecommunications Standard. And that standard
8 provides the basis for how information is -- what
9 information is typically stored in pharmacy data
10 and how that information can be processed. You
11 know, so how we can develop our tools.

12 In addition, we use the medical
13 literature to supplement that information, and also
14 we use electronic health records data to look at
15 how medications are used to help supplement our
16 algorithms as well.

17 So it is a multilayered process of
18 assimilating evidence across multiple, I guess,
19 data sets or sources -- sources is probably the
20 best word.

21 Q. (BY MR. WEINBERGER:) And is that a
22 well-recognized methodology for taking information
23 and data and creating algorithms that then leads to
24 drug-drug interaction, warnings and alerts?

25 MS. FUMERTON: Objection, form.

1 A. Our methods are standard within the
2 health outcomes research field. So we provide --
3 we are not developing novel techniques to develop
4 those algorithms.

5 So I guess, in general, to your
6 question, yes, those are standard methods that we
7 use. Each drug pair will have a different set of
8 attributes that will require additional data
9 elements that we will consider. So some of that is
10 incorporated in our tools and may not have been
11 included in previous or other vendor's systems.

12 Q. (BY MR. WEINBERGER:) Okay. And has
13 that -- has that experience in terms of using data
14 to develop algorithms to create alert warning
15 systems -- does that inform you as to your opinions
16 in this case regarding systems that could have been
17 designed with respect to red flags?

18 A. Yes, it does.

19 Q. How does it --

20 MS. FUMERTON: Object to the form.

21 Q. (BY MR. WEINBERGER:) How does it
22 inform you?

23 MS. FUMERTON: Objection, form.

24 A. So the issues that I addressed in my
25 particular report focused on attributes of

1 so-called red flags and how that information could
2 be -- or is maintained within the defendants' data
3 that they maintain on their servers or within their
4 systems.

5 Q. (BY MR. WEINBERGER:) And so you were
6 asked to address the issue of the feasibility, in
7 this case, of the defendants using their
8 computer -- computerized corporate databases of
9 dispensing data to develop a warning or alert
10 system regarding red flags that would be a tool for
11 use by the pharmacist. Is that true?

12 A. That is, yes.

13 MS. FUMERTON: Objection, form.
14 Leading.

15 Q. (BY MR. WEINBERGER:) And how is it
16 that you know from your experience with respect to
17 drug-drug interaction algorithm development that
18 the development of a red flag alert system is
19 feasible? How is it --

20 MS. FUMERTON: Objection, form.

21 Q. (BY MR. WEINBERGER:) How is it you
22 know that?

23 MS. FUMERTON: Objection, form.
24 Misstates the prior testimony and assumes something
25 he hasn't said.

1 A. Well, I did say that pharmacy
2 systems -- pharmacy data has been standardized for
3 a long time. So my research with respect to
4 drug-drug interactions is built upon that
5 standardization of that data and that information
6 and how that information is collected, stored
7 within the pharmacy systems.

8 So across my career, we have utilized
9 data that have come out of those systems, and have
10 used that information to develop our tools, our
11 evaluation of particular drug pairs and then to
12 inform designing of tools that would hopefully
13 reduce exposure to harmful drug combinations.

14 Q. (BY MR. WEINBERGER:) And how is it
15 that that experience informed you, or did it inform
16 you, as to -- to answer the question of the
17 feasibility of the defendants creating a similar
18 system with respect to red flag warnings?

19 MS. FUMERTON: Objection, form.
20 Objection, leading.

21 A. So the data within those systems, as
22 I mentioned, largely standardized and then -- and
23 standardized for a long time. Therefore, you know,
24 the metrics that are of interest with respect to
25 opioid use, in my opinion, are -- and the ones that

1 I put in my report -- are immediately answerable
2 using those data within those organizations.

3 So there's -- we are not suggesting
4 they create any novel data sets or require new
5 information to be collected in order to be able to
6 inform their systems of what would constitute a
7 potential warning that a pharmacist should pay
8 closer attention with respect to dispensing a
9 medication.

10 These medications are -- are --
11 controlled substance -- controlled substances in
12 general are ones that have a high potential for
13 abuse, misuse and, unfortunately, patient safety.

14 So when I evaluated the information
15 that was presented to me and the key questions I
16 was answering, the notion that, you know, you could
17 create these systems was a resounding yes. These
18 systems, it was possible to create these dashboards
19 and, in fact, it appears that one of the
20 defendants, you know, ran -- built the software
21 program to do such a thing.

22 Whether it was actually used or sent
23 to pharmacies or pharmacists, I am not aware. But
24 the New England Journal of Medicine report or
25 paper, I believe that was Exhibit 3 maybe --

1 Q. This --

2 A. -- the Bestes and Brennan paper,
3 uh-huh, you know, demonstrated that they had those
4 systems available to do those metrics.

5 MR. SWANSON: This is Brian Swanson
6 for Walgreens. I move to strike that as
7 nonresponsive.

8 Q. (BY MR. WEINBERGER:) And you also
9 confirmed that CVS, the CVS SAS program created
10 such a design?

11 A. Yes, it did.

12 Q. Okay. So with respect to the
13 documents that were provided to you by me to review
14 and formulate your opinions with respect to the
15 issues addressed at Page 2 of your report, were you
16 provided with the information about how each of
17 these defendants accumulated dispensing data at the
18 store level and sent, transmitted that data to a
19 centralized corporate data bank?

20 MR. SWANSON: Leading, objection.

21 MS. FUMERTON: He didn't even know,
22 Pete, until you said today that you are the one
23 providing the information. It is an absurd
24 question.

25 Q. (BY MR. WEINBERGER:) You can answer.

1 A. In the depositions that I reviewed
2 were statements from representatives of the company
3 about how they maintained their data systems. And
4 I used that information to make the basis of my
5 report that the analyses that I was suggesting were
6 entirely feasible within those organizations.

7 Q. And you also used your own -- strike
8 that.

9 Did you also use your own personal
10 knowledge from the work that you had done in your
11 research regarding what dispensing data is -- is
12 customarily stored at the corporate level of these
13 national chain pharmacies?

14 A. Yes.

15 MS. FUMERTON: Objection, form.

16 A. I'm sorry. Yes. My prior research
17 experience with -- with these organizations, with
18 at least -- with two of these organizations, CVS
19 Caremark and Walgreens, we used that data
20 collaboratively -- collaboratively with them to
21 generate findings.

22 So I am very aware of the data that
23 they had within their organizations and that it was
24 assimilated across stores within their
25 organization.

1 Q. (BY MR. WEINBERGER:) How is it
2 that -- that dispensing data, national dispensing
3 data, with respect to a retail pharmacy chain like
4 a CVS or Walgreens is -- contains information that
5 the dispensing data at a particular store does not
6 contain? Or how is it different -- let me just ask
7 you that. How is it different? I will stop there.

8 How does it differ?

9 MR. SWANSON: Objection.

10 MS. FUMERTON: Objection, form.

11 A. The data that is available within the
12 store is limited to patients that visit that store,
13 typically, and through -- depending upon the
14 organization, depending -- they potentially could
15 look up data at another store at the patient
16 level -- if -- depending upon their system, and how
17 their system was configured. So I am not -- not
18 making any statements about whether these -- all of
19 these defendants had that capability. That is kind
20 of outside the scope of whether the systems could
21 have been created at the organization level. At
22 the organization level now you are combining data
23 across multiple stores. You are -- the
24 assimilation of that data -- the pharmacists
25 filling the prescriptions are not data analysts,

1 are not necessarily able to run reports realtime in
2 a way that would help them inform the legitimacy of
3 filling a prescription at that point in time.

4 So information about that particular
5 patient across all stores could be provided --
6 could have been provided to the pharmacist
7 realtime, and it could have been specified, not
8 just as a patient profile. It includes every
9 medication. So the pharmacist has to go through
10 line by line trying to figure out which medications
11 are relevant to the opioid prescription that may be
12 presented to them versus which ones are not. So
13 that information could be provided to the
14 pharmacists.

15 The other thing is there's no, you
16 know, guardrails in the data that the pharmacist
17 has provided to them. They don't have a situation
18 whether this is an outlier prescription or not. So
19 the pharmacist is having to make those judgment
20 calls without any supporting tools.

21 So at the pharmacy level, yes,
22 they -- they know some of their patients well,
23 probably, because they come in for prescriptions
24 frequently. But they certainly don't know
25 everybody that walks through the pharmacy door.

1 And if you have a relief pharmacist,
2 they probably, you know, are not familiar with that
3 clientele whatsoever.

4 So having those dashboards available
5 for a pharmacist to look at and say, you know,
6 there's a couple of things that are concerning; I
7 need to resolve this, is -- is -- is data that is
8 maintained at the central pharmacy or the central
9 location across stores, not within stores,
10 necessarily.

11 Q. (BY MR. WEINBERGER:) How about
12 information about prescribers, what is the
13 difference between the data at one store versus
14 data kept at a corporate, centrally-located
15 computer system?

16 MS. FUMERTON: Objection. Form and
17 lack of foundation.

18 MR. SWANSON: Also undisclosed
19 opinion.

20 Q. (BY MR. WEINBERGER:) You can answer.

21 A. Every pharmacy has, when they
22 dispense a medication, a prescriber is associated
23 with that medication. And we have used that data
24 to look at prescribing by the same prescriber or
25 not the same prescriber for drug interactions. So

1 it is possible to use that information for all
2 sorts of things.

3 In this case, in this particular
4 situation, knowing the characteristics of that
5 prescriber with respect to specialty and in
6 relation to other specialists -- other prescribers
7 with that same specialty could have helped inform
8 the pharmacist that this particular prescriber was
9 an outlier relative to his or her peers.

10 And again, I refer back to the
11 analysis conducted by CVS that identified, if I
12 remember correctly, forty-two different prescribers
13 that were excessively prescribing.

14 So pharmacists at the store level are
15 not going to have access to that summary
16 information across prescriptions written by the
17 physician. So they may be familiar with a
18 physician, but they may not know how that clientele
19 for that physician -- so they don't get all the
20 patients for that physician. Typically, patients
21 go lots of different places. And by having more
22 data -- I won't say it is perfect data
23 necessarily -- but more data, they could have
24 helped inform the pharmacist, when filling a
25 prescription, with respect to whether this

1 represented an outlier situation or whether it was
2 within the normal scope of practice.

3 Q. Would centrally located and kept data
4 regarding prescribers also identify patterns of
5 prescribing?

6 MR. SWANSON: Objection, leading.

7 MS. FUMERTON: Object, form. Object
8 to this whole -- object, leading. Object to this
9 whole line of questioning that is not disclosed
10 anywhere in his report.

11 And we have already established
12 earlier on that his expert testimony in this case
13 is what is in the four corners of this report.

14 So I'm not really sure what you are
15 doing here, Pete, but all this testimony that you
16 are eliciting is inappropriate and goes beyond the
17 scope of the cross-examination certainly.

18 MR. WEINBERGER: So --

19 MR. SWANSON: I join that objection.

20 MS. FUMERTON: I never mentioned the
21 words "centrally located prescribers."

22 Q. (BY MR. WEINBERGER:) So in your
23 report on Page 5, you do have the last paragraph
24 where you, in the second sentence, state, "Because
25 of data standardization, analysis could have been

1 done -- could have been performed using measures of
2 variants to identify outlier behavior with respect
3 to, A, quantity per prescription by medication,
4 product and strength."

5 What does that mean?

6 MS. FUMERTON: Object to the form.

7 A. Basically, it refers to whether a
8 medication order is within typical or normal
9 limits. And it could be done at the unique
10 medication level. So thinking of, you know,
11 oxycodone versus hydrocodone versus, you know,
12 benzodiazepines such as Diazepam, what have you,
13 you can look at the strength or quantity and start
14 to get metrics on how that prescription that the
15 pharmacist is trying to evaluate is related to
16 other prescriptions that the pharmacy organization
17 has dispensed to other patients.

18 Q. (BY MR. WEINBERGER:) Can you use
19 that same information to evaluate the prescriber?

20 A. Yes, you can.

21 MR. SWANSON: Objection.

22 MS. FUMERTON: Object to the form.

23 Q. (BY MR. WEINBERGER:) Item C says,
24 "Number of prescriptions written for opiate and
25 other medications by prescriber." How is it that

1 centrally located and collected data from across a
2 pharmacy's stores is an advantage over just
3 information from one store regarding a prescriber?

4 MS. FUMERTON: Objection, form.
5 Objection, leading.

6 A. Well, back to -- so, again, I will
7 show or refer back to the CVS's own SAS program
8 where they did this, and they reported the results
9 in the New England Journal of Medicine,
10 demonstrating that their ability to aggregate the
11 information across stores and -- you know, so I
12 guess across specific medications within that --
13 you know, so -- you know, maybe it is an oxycodone
14 twenty milligram tablet in one prescription, and it
15 is an oxycodone -- I'm sorry, ten milligram tablet
16 in one, and it is Oxycodone 5 in the other.

17 So you would be able to discern
18 patterns of prescribing behavior and, therefore,
19 also look at how that relates to normative practice
20 of medicine within that specialty or subspecialty
21 by the prescriber.

22 Q. (BY MR. WEINBERGER:) So you were
23 asked earlier about your source of information
24 regarding the red flags that you identified in your
25 report, which you identified in your Issues section

1 of your report, Page 2, and in this Page 5 of your
2 report, the paragraph -- this full paragraph,
3 "Creating Opioid Specific Red Flags." Do you
4 remember those questions about your source for the
5 red flags?

6 A. I do.

7 Q. Did you -- you were supplied with a
8 copy of the report of Carmen Catizone, our pharmacy
9 expert?

10 A. Yes, I was.

11 MS. FUMERTON: Objection, form.
12 Pete, you specifically represented that he did not
13 rely on that report in any way, shape or form.

14 Q. (BY MR. WEINBERGER:) Did Dr. -- did
15 Mr. Catizone's report and his description of those
16 red flags confirm for you -- whether you relied on
17 it -- confirm for you the list of red flags that
18 you were utilizing in your analysis?

19 MS. FUMERTON: Objection, form. And
20 objection to the misstatement both to me and to the
21 Court as to the effect of the amended report on
22 Mr. Malone's report, which you said was not
23 influenced in any way, shape or form.

24 To the extent that you are now asking
25 him to say whether or not something confirmed

1 something, that does go to the methodology of his
2 expert report and is completely inappropriate and
3 unethical.

4 MR. WEINBERGER: So you talked about
5 his amended report. I am talking about -- I said
6 that his opinions are not changed by the amended
7 report.

8 Q. (BY MR. WEINBERGER:) I am talking
9 about the report, the original report that was
10 created and sent to you. Did it confirm the list
11 of -- the categories of red flags that you utilized
12 in your analysis?

13 A. It did.

14 MS. FUMERTON: Again, objection.
15 Pete, you represented that the original report was
16 not something that he relied on for purposes of his
17 expert report in email communication, and that is
18 in writing.

19 A. I did not rely on that report for
20 purposes of generating my report. It was provided
21 to me after my report had been submitted. And his
22 question, as I understand it, just to be clear, is
23 did Carmen's report or Carmen's document confirm or
24 support the attributes that I have identified.

25 And by and large, they are largely

1 aligned. His is much more extensive than mine,
2 but --

3 Q. (BY MR. WEINBERGER:) So you -- thank
4 you.

5 MS. FUMERTON: Objection to outside
6 the scope of the direct examination. Again -- or
7 the cross-examination.

8 Pete, if you want to give a
9 deposition of your own witness, which is a little
10 odd, but frankly, whatever, you should have noticed
11 the deposition. We could have fought for it then.
12 But this entire line of questioning goes beyond
13 anything that I asked. Specifically I did not ask
14 a single question about Carmen Catizone.

15 Q. (BY MR. WEINBERGER:) So the -- you
16 were asked whether or not this -- the feasibility
17 of this red flag alert system or this dashboard
18 that you described it as would actually identify an
19 improper prescription. Do you recall that line of
20 questioning?

21 A. I did.

22 Q. What is the -- from a pharmacist's
23 standpoint, what is the purpose of evaluating a
24 prescription based upon red flags?

25 MR. SWANSON: Object to form.

1 MS. FUMERTON: Obviously. Goes
2 beyond his report. He has already established he
3 is not an expert on red flags or the identification
4 of red flags.

5 MR. SWANSON: Calls for opinion --

6 Q. (BY MR. WEINBERGER:) You can answer.

7 A. So the -- this falls under the
8 general rubric of prospective drug utilization
9 review, of which drug-drug interactions is one
10 component and obviously red flags for opioids is
11 another.

12 You know, as I have stated, just to
13 be clear, I am not an expert on generation of red
14 flags. So that is not my area of interest. But my
15 research, we weren't evaluating prescription data
16 for red flags.

17 But that said, the -- the whole
18 purpose of this sort of data provided to the
19 pharmacist -- and when I say "this data," a
20 dashboard that says "there may potentially be a
21 problem," is to allow the pharmacist other tools to
22 determine if this medication or this prescription
23 order would warrant further investigation.

24 Q. (BY MR. WEINBERGER:) Okay. Thanks.

25 THE REPORTER: Okay. On that last

1 answer, did you say, but my research, "we are
2 evaluating" or "we aren't evaluating" prescription
3 data for red flags?

4 A. My research does not evaluate
5 prescription data for red flags. Has not.

6 THE REPORTER: Thank you.

7 A. Yeah, you are welcome, Laura.

8 Q. (BY MR. WEINBERGER:) So in your
9 report and in your testimony you talked about the
10 use of corporate-wide dispensing data aggregated
11 across patients -- aggregated across prescribers
12 and across prescriptions.

13 What is -- would you explain the
14 importance of aggregating that information as
15 relates to your opinions in this case?

16 MS. FUMERTON: Objection, form.
17 Objection, lack of foundation. Objection, goes
18 beyond the scope of his opinion.

19 He is not testifying as to the
20 importance of it. He is asking you -- he has
21 established his opinion is on whether it could have
22 been done, not whether or not it was important to
23 do so.

24 A. Correct.

25 Q. (BY MR. WEINBERGER:) So how is it

1 important to your opinions?

2 A. Correct.

3 Q. That is fine --

4 MS. FUMERTON: He just said correct.
5 He hasn't established -- he just said correct to
6 what I said, which is that he has not said and does
7 not have an opinion that it is important to
8 aggregate information.

9 Q. (BY MR. WEINBERGER:) So let me
10 rephrase the question. You testified about
11 aggregating this data as relates to patients'
12 prescriptions and prescribers, correct? You
13 testified about that --

14 A. Yes.

15 Q. -- in your examination. How is
16 that --

17 MS. FUMERTON: Object to the form and
18 leading. I was just requesting that I have --

19 Q. (BY MR. WEINBERGER:) How is that
20 relevant --

21 MS. FUMERTON: Dr. Malone, if you
22 could give me a second to object a second after his
23 question, that would be helpful.

24 THE REPORTER: Hold on. Hold on.
25 Hold on. I can't get y'all talking at one time.

1 "Object to the form." Then what else
2 did you say?

3 MS. FUMERTON: That is what I was
4 just saying. I was just requesting that I have an
5 opportunity to object because Dr. Malone is jumping
6 in and answering these questions before they
7 finish. So I just need an opportunity to object so
8 I am not speaking over either Pete or Dr. Malone.

9 MR. WEINBERGER: We will give you
10 plenty of time to state your objection, which you
11 have told me you are not supposed to be saying
12 anything but objection as to form.

13 Q. (BY MR. WEINBERGER:) But anyway,
14 let's go back.

15 In the course of answering
16 Ms. Fumerton's questions, you talked about the
17 importance of aggregating information utilizing
18 corporate dispensing data as relates to patients,
19 prescriptions and prescribers. Do you recall that
20 testimony?

21 A. Yes.

22 MS. FUMERTON: Objection, form.
23 Misstates the prior testimony.

24 Q. (BY MR. WEINBERGER:) And how is that
25 aggregation of data relevant to your opinions

1 regarding the feasibility of these defendants
2 creating an alert system based upon their own
3 dispensing data?

4 MS. FUMERTON: Objection, form.
5 Objection, lack of foundation. He hasn't
6 established that it is relevant.

7 Q. (BY MR. WEINBERGER:) Go ahead, you
8 can answer.

9 MS. FUMERTON: Objection, leading
10 him.

11 Q. (BY MR. WEINBERGER:) You can answer.

12 A. It is a key component of my report
13 that this data be able to be aggregated across the
14 organizations' business units, i.e., pharmacies, in
15 order to give, again, the pharmacists an accurate
16 picture that not only reflects their own store but
17 reflects the prescribers' behavior beyond their
18 store, the utilization of that medication beyond
19 their store, the utilization -- or the quantity and
20 dose or morphine equivalence beyond their limited
21 pharmacy practice at that facility.

22 So that ability to accumulate that
23 information and provide some metrics back to the
24 pharmacist is necessary to be done at the corporate
25 level, not at the -- can't be done -- cannot be

1 efficiently done at the store level and would
2 require a different set of tools within the
3 pharmacy that probably are not available to the
4 day-to-day practicing pharmacist.

5 MR. WEINBERGER: Thank you,
6 Dr. Malone. Those are all the questions I have.

7 MS. FUMERTON: I think we need to
8 take a five- or ten-minute break, and then I am
9 sure we are going to have a series of additional
10 questions. So why don't we take a five- or
11 ten-minute break, then we will get back.

12 MR. WEINBERGER: Can the videographer
13 tell me what -- how much time was taken by
14 Ms. Fumerton, please, and how much time I took?

15 THE VIDEOGRAPHER: Well, yes. She
16 stopped at the -- she -- at the last break, we were
17 at six hours and thirteen minutes. And then you
18 began. So we are on the record now for fifty-one
19 minutes. And you and another gentleman were
20 questioning.

21 MR. WEINBERGER: How much -- do you
22 know how many minutes I spent?

23 THE VIDEOGRAPHER: I would have to
24 look through the log here. Give me a second.

25 MR. WEINBERGER: Because I think you

1 included Josh's questions.

2 THE VIDEOGRAPHER: Yeah. Yeah. Let
3 me look through the log.

4 THE REPORTER: Do you want to go off
5 the record?

6 MR. WEINBERGER: Yeah, we can go off
7 the record.

8 THE VIDEOGRAPHER: We can go off the
9 record at 7:13.

10 (Whereupon, a break was had from 7:13
11 p.m. until 7:23 p.m. EDT)

12 THE VIDEOGRAPHER: We are back on the
13 record at 7:23.

14

15 REEXAMINATION BY MS. FUMERTON:

16 Q. Dr. Malone, do you understand that
17 you were under oath when you were answering
18 questions from Mr. Weinberger?

19 A. Yes.

20 Q. Do you understand that you are still
21 under oath now?

22 A. I do.

23 Q. Did you have telephone calls with
24 Mr. Weinberger during any breaks today?

25 A. When he was -- not at the break.

1 Well, I guess it was during the break when he
2 couldn't get on the -- or his internet crashed, he
3 called me because we were trying to reach him.

4 Q. Did you have any other?

5 A. Conversations, no, I did not speak or
6 communicate with Mr. Weinberger via phone, email,
7 text or otherwise.

8 Q. Did you communicate with anybody
9 else?

10 A. No, ma'am.

11 Q. Did you take notes during your
12 testimony today?

13 A. No, ma'am.

14 Q. Did you have any documents other than
15 the exhibits that we marked in front of you today?

16 A. The -- I was trying to recall my own
17 error with regards to the NCPDP Script issue that
18 you raised, the Telecommunications Standard. So I
19 pulled up a PowerPoint presentation that I had used
20 during one of the breaks just to refresh my memory
21 as to what those standards were.

22 MS. FUMERTON: I am going to formally
23 request that we get a copy of that PowerPoint
24 presentation that Dr. Malone reviewed.

25 Q. (BY MS. FUMERTON:) Can you describe

1 what the PowerPoint presentation is?

2 A. Sure. Would you like to see it on
3 screen?

4 Q. Sure.

5 A. Okay.

6 (Exhibit 10 was marked for
7 identification after the deposition
8 was concluded. The reporter was
9 supplied the requested document via
10 email by Mr. Weinberger.)

11 MS. FUMERTON: And actually, why
12 don't we mark this as -- what are we at, Exhibit
13 10?

14 MS. ZINSMASER: That is where we are
15 at. I don't have the ability to mark this because
16 I don't have the document.

17 MR. WEINBERGER: I have us as we are
18 up to Exhibit 8. Maybe I am missing an exhibit.

19 MS. FUMERTON: Exhibit 9 was the
20 spreadsheet.

21 MR. WEINBERGER: Oh, yeah, yeah.
22 Yes. Right. You are right.

23 Q. (BY MS. FUMERTON:) How many pages is
24 this document?

25 A. I'm not sure how many slides are in

1 it.

2 Q. Did you create this document?

3 A. I did. Thirty slides.

4 Q. When did you create this document?

5 A. Probably three or four years ago.

6 Part of a class I taught on pharmacy informatics.

7 Q. Did you rely on this document for
8 purposes of your expert opinion today?

9 A. I did pull it up, yeah. And the --
10 the page -- it confused me, I guess, when I was
11 putting my document together. So these are all
12 data points that are used in pharmacy systems, but
13 this is a slide that confused me. I misread --
14 when I was referencing the standard, I misread this
15 particular document.

16 So I used the Script Standard Version
17 5.0. It actually should have been
18 Telecommunications Standard 5.1 in my document.
19 I'll correct that for the record.

20 Q. Okay. So I just want to make sure
21 what your testimony is now. So your current
22 testimony -- and let me pull your expert report
23 out. Can you please keep it on that page that you
24 are on?

25 A. Sure. I will pull the screen up.

1 Q. So in your expert report on Page 4,
2 you say that you reviewed the National Council for
3 Prescription Drug Programs, NCPDP, Technical
4 Standard documentation called Script V5.0.

5 And that is on Page 4 of your report,
6 correct?

7 A. Yes. And that is the error I was
8 trying to correct.

9 Q. And so what is the correct statement
10 that you think it should say?

11 A. It should say Telecommunications
12 Standard Version 5.1.

13 Q. And you are certain that is the right
14 one this time?

15 A. Yes, ma'am.

16 Q. What is Telecommunications Standard
17 D.0?

18 A. I'm sorry. I think you cut out.

19 Q. What is Telecommunications Standard
20 D.0?

21 A. D, as in delta, .0?

22 Q. Uh-huh.

23 A. Are you deriving that from what is on
24 my screen?

25 Q. Nope.

1 A. I am not familiar with D.O.

2 MS. FUMERTON: You can take down this
3 document. But as I said before, I would request a
4 copy. So if you can send a copy of that to
5 Mr. Weinberger, we are marking that as Exhibit 10.
6 So if the court reporter would like us to do it a
7 different way, we can talk off the record about how
8 to make sure we get it on the record.

9 Q. (BY MS. FUMERTON:) During the course
10 of your deposition today, is there any other
11 documents that you researched?

12 A. No.

13 Q. Mr. Weinberger, during his lengthy
14 direct examination of you, asked you a series of
15 questions about your methodology with respect to
16 your research involving DDI, correct?

17 A. Yes, he did.

18 Q. You have never developed the specific
19 algorithms that you say that the pharmacies in this
20 case could have developed, correct?

21 A. No, I have not written that code, no.

22 Q. You have never attempted to write
23 that code, correct?

24 A. That's correct.

25 Q. You are not aware of anybody else

1 that has attempted to write that code, correct?

2 A. No.

3 Q. You are not aware of any
4 peer-reviewed journals discussing creating such a
5 system, correct?

6 A. So the publication in the New England
7 Journal of Medicine by the CVS authors used the
8 code to do those things that I cited in my report.

9 MS. FUMERTON: I am moving to strike
10 that as nonresponsive.

11 MR. SWANSON: Join.

12 A. So you asked me if anybody else had
13 used peer-reviewed code to do those activities.
14 And yes, there is a report out there.

15 Q. (BY MS. FUMERTON:) Okay. So but
16 earlier you testified that what was done in the New
17 England Journal of Medicine article was not
18 equivalent to the dashboard that you were talking
19 about that the pharmacies could create, correct?

20 MR. WEINBERGER: Objection, form.

21 A. So when you say "code," that implies
22 one specific meaning. A dashboard is a completely
23 different thing. I think you asked me about code.
24 Could you repeat the question?

25 Q. (BY MS. FUMERTON:) Well, I am

1 actually asking you about algorithm. I think you
2 started to use the word "code."

3 A. Okay.

4 Q. So let's go back. I had asked you
5 earlier, and if you need to correct this testimony,
6 that is fine, too, since you are correcting other
7 testimony.

8 But earlier I had asked you whether
9 or not the system that CVS had described in that
10 article was equivalent to the dashboards that you
11 are opining in your report the pharmacy defendants
12 could have created.

13 And you testified no, that wasn't; it
14 was a portion of what you think they could do, but
15 it was not equivalent to what you were opining was
16 what they could do, correct?

17 A. Yes.

18 Q. Okay. So what I am asking you -- so
19 you are standing by that testimony. You are not
20 adopting -- you are saying that what the pharmacy
21 defendants could have done is what CVS had done in
22 that article, correct?

23 A. You talk so fast, sometimes it is
24 hard for me to capture everything. Say it again.

25 Q. Yeah. So you are standing by your

1 prior testimony, when I was originally asking you a
2 question, that the program described in Exhibit 3
3 was not equivalent to the dashboards that you were
4 opining in your report the pharmacy defendants
5 could have created, correct?

6 A. Correct.

7 Q. And so my question, to be very
8 specific, is not whether anybody, if someone has
9 done some portion of this. I am asking you are you
10 aware of any instance on which there is the system
11 that you are describing in your report that has
12 been evaluated in a peer-reviewed journal?

13 MR. WEINBERGER: Objection, form.

14 A. No.

15 Q. (BY MS. FUMERTON:) Do you know of
16 anybody who has evaluated that other than you?

17 MR. WEINBERGER: Objection, form.

18 A. I believe -- so Carmen Catizone's
19 report goes beyond what I had opined. So there --
20 in terms of -- are you saying put in -- so let's be
21 clear.

22 Are we talking developed as in
23 conceptualized, or are we talking in terms of
24 production, actually used in a pharmacy
25 environment? Because I think we're referring to --

1 Q. (BY MS. FUMERTON:) Well, let's start
2 with the latter first.

3 A. Conceptualized.

4 Q. We have already established it has
5 never been used in a pharmacy environment, correct?

6 A. Fair enough, yes.

7 Q. Okay. So I am talking about what you
8 are theorizing in your report is a system that
9 could have been created. Are you aware of anybody
10 else who has theorized that the same system that
11 you are opining about in your report is something
12 that the pharmacy defendants could have done?

13 MR. WEINBERGER: Objection, form.

14 A. Yes.

15 Q. (BY MS. FUMERTON:) And who is that?

16 A. Mr. Catizone's report indicates that
17 those -- based upon my reading of his report, seems
18 to suggest that those processes are entirely
19 capable within the pharmacy system's data that I
20 alluded to.

21 Q. So you think that Dr. Catizone is
22 giving the same expert opinion in this case that
23 you are?

24 A. No.

25 Q. Do you think that Dr. Catizone is

1 giving a broader expert opinion, that your expert
2 opinion is subsumed within his report; is that
3 correct?

4 A. Some components are, yes.

5 Q. Is the entirety of it subsumed within
6 Dr. Catizone's report?

7 A. No.

8 Q. So I am asking again, for the
9 dashboard, which has lots of different attributes
10 that you have described --

11 A. Uh-huh.

12 Q. -- are you aware of anybody else who
13 has opined that all of those different attributes
14 could be combined into a single dashboard to be
15 used by a retail chain pharmacy?

16 MR. WEINBERGER: Objection, form.

17 A. No, I am not. I am sorry. I don't
18 want to contradict myself because it sounds like
19 you are asking the same question you asked me a
20 minute ago when I mentioned Carmen Catizone.

21 Q. (BY MS. FUMERTON:) No.

22 A. Okay. So please restate the
23 question.

24 Q. (BY MS. FUMERTON:) I asked you, do
25 you think that Dr. Catizone is giving a broader

1 expert opinion, that your expert opinion is
2 subsumed within his report. You said some
3 components are. I asked you if the entirety of
4 your opinions are subsumed within Dr. Catizone's
5 report. You testified no.

6 Then I asked you, so I am asking
7 again, for the dashboard you are opining that the
8 retail pharmacy defendants could have created, are
9 you aware of anybody else that has opined that all
10 of those different attributes could be combined
11 into a single dashboard to be used by a retail
12 chain pharmacy. Your answer was no, correct?

13 A. That's correct, yeah.

14 (Pause.)

15 MS. FUMERTON: I have a note
16 someplace, so I'm going to go off of memory. Does
17 anybody else have any other questions? Because
18 otherwise, I just have a request.

19 Okay. My request is that you
20 preserve the notes that you said you took in
21 connection with creating your expert report and
22 that you preserve the financial records for your
23 consulting company. And with that, I don't have
24 any further questions.

25 MR. WEINBERGER: Dr. Malone, I have

1 no further questions. Thank you for your testimony
2 today and for your patience, your professionalism.
3 And we will be talking.

4 A. Okay.

5 MS. FUMERTON: Thank you.

6 A. Sorry to make it a late day for
7 everybody. Have a good evening.

8 MR. WEINBERGER: That's not your
9 fault.

10 THE VIDEOGRAPHER: We will go off the
11 record at 7:38.

12

13 (Deposition concluded at 7:38 p.m. EDT)

14

15 FURTHER THE DEPONENT SAITH NOT

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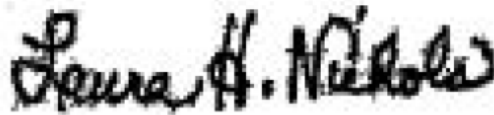
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C E R T I F I C A T E

STATE OF ALABAMA
JEFFERSON COUNTY

I hereby certify that the above and foregoing deposition was taken down by me in stenotypy, and the questions and answers thereto were reduced to typewriting under my supervision, and that the foregoing represents a true and correct transcript of the deposition given by said witness upon said hearing, to the best of my ability.

I further certify that I am neither of counsel nor of kin to the parties to the action, nor am I in anywise interested in the result of said cause.



LAURA H. NICHOLS

Commissioner-Notary Public, State of AL

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June 3, 2021

To: Peter H. Weinberger, Esq.

Case Name: National Prescription Opiate Litigation - Track 3

Veritext Reference Number: 4615080

Witness: Daniel Charles Malone, Ph.D. Deposition Date: 5/28/2021

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4615080

CASE NAME: National Prescription Opiate Litigation - Track 3

DATE OF DEPOSITION: 5/28/2021

WITNESS' NAME: Daniel Charles Malone, Ph.D.

In accordance with the Rules of Civil
Procedure, I have read the entire transcript of
my testimony or it has been read to me.

I have made no changes to the testimony
as transcribed by the court reporter.

Date Daniel Charles Malone, Ph.D.

Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn
Statement; and
Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4615080

CASE NAME: National Prescription Opiate Litigation - Track 3

DATE OF DEPOSITION: 5/28/2021

WITNESS' NAME: Daniel Charles Malone, Ph.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date Daniel Charles Malone, Ph.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections
in the appended Errata Sheet;
They signed the foregoing Sworn
Statement; and
Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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ERRATA SHEET
VERITEXT LEGAL SOLUTIONS MIDWEST
ASSIGNMENT NO: 4615080

PAGE/LINE(S) / CHANGE /REASON

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DAY OF _____, 20____ .

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Commission Expiration Date

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[agree - answer]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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